

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PrSKYRIZI®**

#### **150 mg/mL risankizumab injection, solution for subcutaneous injection**

Read this carefully before you start taking Skyrizi and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Skyrizi.

#### **What is Skyrizi used for?**

- Skyrizi is a prescription medicine used to treat adults with moderate to severe plaque psoriasis, an inflammatory condition affecting the skin and nails. Plaque psoriasis can cause raised, thick, red and scaly patches (“psoriatic lesions”) that can appear anywhere on your body.
- Skyrizi is used to treat adults with active psoriatic arthritis. Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. Psoriatic arthritis can cause pain, swelling and stiffness in the joints, in addition to a disruption in daily activities and fatigue. If you have active psoriatic arthritis, you will be given Skyrizi alone or in combination with a conventional Disease Modifying Anti-Rheumatic Drug (DMARD), such as methotrexate.
- Skyrizi is used to treat adults with moderate to severe Crohn’s disease, an inflammatory condition affecting the gastrointestinal tract that can cause abdominal pain, severe diarrhea, fatigue, and even weight loss.

#### **How does Skyrizi work?**

Skyrizi contains the active substance risankizumab. This medicine works by stopping a protein in the body called IL-23, which causes inflammation.

##### **Plaque Psoriasis**

Skyrizi reduces inflammation and can therefore help to improve skin clearance and to reduce symptoms of psoriasis such as burning, itching, pain, and redness.

##### **Psoriatic Arthritis**

Skyrizi reduces the inflammation and can therefore help to reduce pain, stiffness, and swelling in and around your joints, pain and stiffness in your spine, psoriatic skin rash, psoriatic nail damage, and it may limit damage to the bone and cartilage in your joints. These effects can ease your normal daily activities, reduce tiredness, and improve your quality of life.

##### **Crohn’s Disease**

Skyrizi reduces the inflammation and can therefore help to reduce the signs and symptoms of your disease like abdominal pain, severe diarrhea, fatigue, and even weight loss.

If you have active Crohn’s disease you may first be given other medicines. If these medicines do not work well enough, you will be given Skyrizi to treat your Crohn’s disease.

#### **What are the ingredients in Skyrizi?**

Medicinal ingredient: risankizumab

Non-medicinal ingredients: acetic acid, polysorbate 20, sodium acetate trihydrate, trehalose dihydrate, and water for injection

**Skyrizi comes in the following dosage forms:**

Plaque Psoriasis and Psoriatic Arthritis

Pre-filled pen and pre-filled syringe with 150 mg of risankizumab in 1 mL of solution for injection (150 mg/mL).

Skyrizi 150 mg/mL is a clear and colourless to yellow liquid in a pre-filled pen or pre-filled syringe with needle guard. Each carton contains 1 pre-filled pen or 1 pre-filled syringe.

Crohn's Disease

Vial with 600 mg of risankizumab in 10 mL of solution for infusion (60 mg/mL). Skyrizi 60 mg/mL is a clear and colourless to slightly yellow liquid in a single-use vial. Each carton contains 1 vial.

Pre-filled cartridge with 360 mg of risankizumab in 2.4 mL of solution for subcutaneous injection (150 mg/mL). Skyrizi 150 mg/mL is a clear and colourless to yellow liquid in a pre-filled cartridge. Each carton contains 1 pre-filled cartridge with 1 on-body injector.

**Do not use Skyrizi if:**

- You have had a serious allergic reaction to risankizumab or any of the other ingredients of Skyrizi (See **What are the ingredients in Skyrizi?**). Symptoms of serious allergic reactions include: trouble breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat.
- If any of these symptoms occur during treatment with Skyrizi, stop taking Skyrizi and get emergency medical help right away.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Skyrizi. Talk about any health conditions or problems you may have, including if you:**

- currently have an infection or if you have an infection that keeps coming back. Skyrizi may lower your ability to fight infections and may increase your risk of infections.
- have tuberculosis (TB) or have been in close contact with someone with TB.
- have recently received or plan to receive an immunization (vaccine). You should not be given certain types of vaccines (called 'live vaccines') while using Skyrizi.

**Talk to your healthcare professional right away if you have any of the symptoms of serious infection:**

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath
- cough
- blood in your phlegm (mucus)
- warm, red or painful skin, sores on your body different from your psoriasis, or a painful skin rash with blisters
- muscle aches
- weight loss

**Talk to your healthcare professional right away if you have any of the signs or symptoms of an allergic reaction, including:**

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

**Other warnings you should know about:**

Skyrizi is not approved for children and adolescents with plaque psoriasis, psoriatic arthritis or Crohn's disease under 18 years of age. This is because it has not been studied in this age group.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This is because it is not known if Skyrizi can harm your unborn baby. If you are a woman of childbearing potential, use adequate contraception while using Skyrizi and for at least 20 weeks after the last Skyrizi dose. Talk to your doctor about your contraception options.

If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine. It is not known if Skyrizi passes into breast milk. You and your doctor should decide if you will breastfeed while using Skyrizi.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**How to take Skyrizi:**

- Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure how to use this medicine.
- Skyrizi is injected under your skin (called "subcutaneous injection") or given by your doctor through a vein in the arm (called "intravenous infusion").
- You and your doctor, pharmacist or nurse will decide if you should inject Skyrizi yourself. Do not inject yourself with this medicine unless you have been trained by your doctor, pharmacist or nurse. A caregiver may also give your injections after training. The AbbVie Care Support Program is also available to you if you require assistance with injections should you prefer nurse-administered injections. Information about the support services can be obtained by calling the AbbVie Care Support Program at 1-866-848-6472.
- For the pre-filled pen, take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **30 to 90 minutes** before injecting.
- For a more comfortable injection with the pre-filled syringe, take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **15 to 30 minutes** before injecting.
- For the pre-filled cartridge, take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **45 to 90 minutes** before injecting.
- Read the "**Instructions for Use**" before injecting Skyrizi yourself.

**Usual dose:**

Adults with Plaque Psoriasis and Psoriatic Arthritis

The dose is 150 mg given as one 150 mg injection. After the first dose, you will have the next dose 4 weeks later, and then every 12 weeks.

Do not stop using Skyrizi without talking to your doctor first. If you stop treatment, your symptoms may come back.

Adults with Crohn’s disease

You will begin treatment with Skyrizi with a starting dose which will be given by your doctor through a drip in your arm (intravenous infusion) over at least 60 minutes (refer to the Patient Medication Information for 60 mg/mL risankizumab for injection for intravenous infusion).

**Starting doses**

	How much?	When?
Starting doses	600 mg	When your doctor tells you
	600 mg	4 weeks after 1 <sup>st</sup> dose
	600 mg	4 weeks after 2 <sup>nd</sup> dose

Afterwards, you will receive or you will inject yourself Skyrizi as an injection under your skin (subcutaneous injection) using an on-body injector with pre-filled cartridge.

**Maintenance doses**

	How much?	When?
1 <sup>st</sup> maintenance dose	360 mg	4 weeks after the last starting dose (at Week 12)
Further doses	360 mg	Every 8 weeks, starting after the 1 <sup>st</sup> maintenance dose

**Overdose:**

If you think you, or a person you are caring for, have taken too much Skyrizi, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed dose:**

If you forgot to take Skyrizi, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. Talk to your doctor if you are not sure what to do.

**What are possible side effects from using Skyrizi?**

These are not all the possible side effects you may have when taking Skyrizi. If you experience any side effects not listed here, contact your doctor. Your doctor will decide if you can keep using Skyrizi.

Tell your doctor, pharmacist or nurse if you get any of the following side effects:

**Very common:** may affect more than 1 in 10 people

- upper respiratory infections with symptoms such as sore throat and stuffy nose

**Common:** may affect up to 1 in 10 people

- feeling tired
- fungal skin infection
- injection site reactions
- headache
- itching
- burning when you urinate or urinating more often than normal

**Uncommon:** may affect up to 1 in 100 people

- small raised red bumps on the skin

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Uncommon</b>			
Serious Infections: Fever, flu-like symptoms, night sweats, cough, blood in your phlegm (mucus), warm, red or painful skin, muscle aches, weight loss		√	√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your doctor, pharmacist or nurse.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

Keep this medicine out of reach and sight of children.

Do not use this medicine after the expiration date which is stated on the pen, syringe, or cartridge label and outer carton after 'EXP'.

Store in a refrigerator between 2 and 8 °C (36 and 46 °F). Do not freeze. Do not use if Skyrizi has been frozen.

Keep in the original carton in order to protect from light.

If needed, you may also store Skyrizi 150 mg/mL pre-filled pen or pre-filled syringe out of the refrigerator (up to a maximum of 25°C [77°F]) for up to 24 hours in the original carton to protect from light.

The liquid should look clear to yellow. The liquid may contain tiny white or clear particles. Do not use if liquid is cloudy or contains flakes or large particles.

This medicine is for single use only. Ask your doctor, pharmacist or nurse how to throw away used pens, syringes, and cartridges safely.

**If you want more information about Skyrizi:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.abbvie.ca](http://www.abbvie.ca)), or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

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## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PrSKYRIZI®**

#### **60 mg/mL risankizumab for injection, solution for intravenous infusion**

Read this carefully before you start taking Skyrizi. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Skyrizi.

#### **What is Skyrizi used for?**

Skyrizi is a prescription medicine used to treat adults with moderate to severe Crohn's disease, an inflammatory condition affecting the gastrointestinal tract that can cause abdominal pain, severe diarrhea, fatigue, and even weight loss.

#### **How does Skyrizi work?**

Skyrizi contains the active substance risankizumab. This medicine works by stopping a protein in the body called IL-23, which causes inflammation.

Skyrizi reduces the inflammation and can therefore help to reduce the signs and symptoms of your disease like abdominal pain, severe diarrhea, fatigue, and even weight loss.

If you have active Crohn's disease you may first be given other medicines. If these medicines do not work well enough, you will be given Skyrizi to treat your Crohn's disease.

#### **What are the ingredients in Skyrizi?**

Medicinal ingredient: risankizumab

Non-medicinal ingredients: acetic acid, polysorbate 20, sodium acetate trihydrate, trehalose dihydrate, and water for injection

#### **Skyrizi comes in the following dosage forms:**

Vial with 600 mg of risankizumab in 10 mL of solution for infusion (60 mg/mL). Skyrizi 60 mg/mL is a clear and colourless to slightly yellow liquid in a single-use vial. Each carton contains 1 vial.

#### **Do not use Skyrizi if:**

- You have had a serious allergic reaction to risankizumab or any of the other ingredients of Skyrizi (**See What are the ingredients in Skyrizi?**). Symptoms of serious allergic reactions include: trouble breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat.
- If any of these symptoms occur during treatment with Skyrizi, stop taking Skyrizi and get emergency medical help right away.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Skyrizi. Talk about any health conditions or problems you may have, including if you:**

- currently have an infection or if you have an infection that keeps coming back. Skyrizi may lower your ability to fight infections and may increase your risk of infections.
- have tuberculosis (TB) or have been in close contact with someone with TB.

- have recently received or plan to receive an immunization (vaccine). You should not be given certain types of vaccines (called ‘live vaccines’) while using Skyrizi.

**Talk to your healthcare professional right away if you have any of the symptoms of serious infection:**

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath
- cough
- blood in your phlegm (mucus)
- warm, red or painful skin, sores on your body
- muscle aches
- weight loss

**Talk to your healthcare professional right away if you have any of the signs or symptoms of an allergic reaction, including:**

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

**Other warnings you should know about:**

Skyrizi is not approved for children and adolescents with Crohn’s disease under 18 years of age. This is because it has not been studied in this age group.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This is because it is not known if Skyrizi can harm your unborn baby. If you are a woman of childbearing potential, use adequate contraception while using Skyrizi and for at least 20 weeks after the last Skyrizi dose. Talk to your doctor about your contraception options.

If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine. It is not known if Skyrizi passes into breast milk. You and your doctor should decide if you will breastfeed while using Skyrizi.

**Tell your healthcare professional about all the medicines you are using, have recently used or might use, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**How to take Skyrizi:**

You will begin treatment with Skyrizi with a starting dose which will be given to you by a qualified healthcare professional intravenously (through a vein) over at least 60 minutes.

**Usual dose:**

Starting doses

	<b>How much?</b>	<b>When?</b>
Starting doses	600 mg	When your doctor tells you
	600 mg	4 weeks after 1 <sup>st</sup> dose
	600 mg	4 weeks after 2 <sup>nd</sup> dose



Afterwards, you will receive a different dose of Skyrizi as maintenance therapy by an injection under your skin (subcutaneous injection) using an on-body injector with pre-filled cartridge (refer to the Patient Medication Information for 150 mg/mL risankizumab injection for subcutaneous injection).

#### Maintenance doses

	How much?	When?
<b>1<sup>st</sup> maintenance dose</b>	360 mg	4 weeks after the last starting dose (at Week 12)
<b>Further doses</b>	360 mg	Every 8 weeks, starting after the 1 <sup>st</sup> maintenance dose

#### Overdose:

If you think you, or a person you are caring for, have taken too much Skyrizi, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

#### Missed dose:

If you forget or miss the appointment for any of your doses, contact your doctor to reschedule your appointment as soon as you remember.

Do not stop using Skyrizi without talking to your doctor first. If you stop treatment, your symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

#### What are possible side effects from using Skyrizi?

These are not all the possible side effects you may feel when taking Skyrizi. If you experience any side effects not listed here, contact your doctor. Your doctor will decide if you can keep using Skyrizi.

Tell your doctor, pharmacist or nurse if you get any of the following side effects:

**Very common:** may affect more than 1 in 10 people

- upper respiratory infections with symptoms such as sore throat and stuffy nose

**Common:** may affect up to 1 in 10 people

- feeling tired
- fungal skin infection
- injection site reactions
- headache
- itching
- burning when you urinate or urinating more often than normal

**Uncommon:** may affect up to 1 in 100 people

- small raised red bumps on the skin

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Uncommon</b>			
Serious Infections: Fever, flu-like symptoms, night sweats, cough, blood in your phlegm (mucus), warm, red or painful skin, muscle aches, weight loss		√	√
Liver problems: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite, itching		√	√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your doctor, pharmacist or nurse.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

Visiting the Web page on [Adverse Reaction Reporting \(https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or

Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage (instructions for healthcare professionals only):

Skyrizi 600 mg concentrate for solution for infusion is given in a hospital or clinic and patients should not need to store or handle it.

Keep this medicine out of reach and sight of children.

Do not use this medicine after the expiration date which is stated on the vial label and outer carton after 'EXP'.

Store in a refrigerator between 2 and 8 °C (36 and 46 °F). Do not freeze. Do not use if Skyrizi has been frozen.

Keep in the original carton in order to protect from light.

Do not shake the Skyrizi vial. Prolonged vigorous shaking can damage the medicine.

The liquid should look clear to slightly yellow. The liquid may contain tiny white or clear particles. Do not use if liquid is cloudy or contains flakes or large particles.

**The following information is intended for healthcare professionals only**

Instructions for intravenous induction dosing regimen

1. Skyrizi should be prepared by a healthcare professional using aseptic technique prior to labeled expiry date.
2. Skyrizi medicinal product must be diluted before administration.
3. Skyrizi for intravenous administration must be diluted into an intravenous infusion bag or glass bottle containing 5% dextrose in water (D5W) (600 mg/10 mL in 100 mL, or 250 mL or 500 mL) to a final drug concentration of approximately 1.2 mg/mL to 6 mg/mL.
4. The solution in the vial and dilutions should not be shaken.
5. Once diluted, the solution can be stored (protected from direct and indirect light) at room temperature between 15 to 30°C (59 to 86°F) for administration within 8 hours (including the infusion period) or, refrigerated immediately for up to 20 hours between 2 and 8 °C (36 and 46 °F) for later administration. Once removed from the refrigerated storage, the diluted solution should be administered within 8 hours (including infusion period). Do not freeze.
6. Prior to the start of the intravenous infusion, the content of the infusion bag or glass bottle should be at room temperature.
7. Infuse the diluted solution over a period of at least one hour.
8. Skyrizi vial solution should not be administered concomitantly in the same intravenous line with other medicinal products.
9. Each vial is for single use only and any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**If you want more information about Skyrizi:**

Talk to your healthcare professional.

Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.abbvie.ca](http://www.abbvie.ca)), or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

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## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PrSKYRIZI®**

#### **90 mg/mL risankizumab injection, solution for subcutaneous injection**

Read this carefully before you start taking **Skyrizi** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Skyrizi**.

#### **What is Skyrizi used for?**

- Skyrizi is a prescription medicine used to treat adults with moderate to severe plaque psoriasis, an inflammatory condition affecting the skin and nails. Plaque psoriasis can cause raised, thick, red and scaly patches (“psoriatic lesions”) that can appear anywhere on your body.
- Skyrizi is used to treat adults with active psoriatic arthritis. Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. Psoriatic arthritis can cause pain, swelling and stiffness in the joints, in addition to a disruption in daily activities and fatigue. If you have active psoriatic arthritis, you will be given Skyrizi alone or in combination with a conventional Disease Modifying Anti-Rheumatic Drug (DMARD), such as methotrexate.

#### **How does Skyrizi work?**

##### **Plaque Psoriasis**

Skyrizi contains the active substance risankizumab. This medicine works by stopping a protein in the body called IL-23, which causes inflammation. It also improves skin clearance and reduces symptoms of psoriasis such as burning, itching, pain, and redness.

##### **Psoriatic Arthritis**

Skyrizi reduces the inflammation and can therefore help to reduce pain, stiffness, and swelling in and around your joints, pain and stiffness in your spine, psoriatic skin rash, psoriatic nail damage, and it may limit damage to the bone and cartilage in your joints. These effects can ease your normal daily activities, reduce tiredness, and improve your quality of life.

#### **What are the ingredients in Skyrizi?**

Medicinal ingredients: risankizumab

Non-medicinal ingredients: disodium succinate hexahydrate, polysorbate 20, sorbitol, succinic acid, and water for injection.

#### **Skyrizi comes in the following dosage forms:**

Pre-filled syringe with 75 mg of risankizumab in 0.83 mL of solution for injection (90 mg/mL).

Skyrizi is a clear and colourless to slightly yellow liquid in a pre-filled syringe with needle guard. Each carton contains 2 pre-filled syringes.

**Do not use Skyrizi if:**

- You have had a serious allergic reaction to risankizumab or any of the other ingredients of Skyrizi (See **What are the ingredients in Skyrizi?**). Symptoms of serious allergic reactions include: trouble breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat.
- If any of these symptoms occur during treatment with Skyrizi, stop taking Skyrizi and get emergency medical help right away.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Skyrizi. Talk about any health conditions or problems you may have, including if you:**

- currently have an infection or if you have an infection that keeps coming back. Skyrizi may lower your ability to fight infections and may increase your risk of infections.
- have tuberculosis (TB) or have been in close contact with someone with TB.
- have recently received or plan to receive an immunization (vaccine). You should not be given certain types of vaccines (called 'live vaccines') while using Skyrizi.

**Talk to your healthcare professional right away if you have any of the symptoms of serious infection:**

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath
- cough
- blood in your phlegm (mucus)
- warm, red or painful skin, sores on your body different from your psoriasis, or a painful skin rash with blisters
- muscle aches
- weight loss

**Talk to your healthcare professional right away if you have any of the symptoms of an allergic reaction, including:**

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

**Other warnings you should know about:**

Skyrizi is not approved for children and adolescents under 18 years of age. This is because it has not been studied in this age group.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This is because it is not known if Skyrizi can harm your unborn baby. If you are a woman of childbearing potential, use adequate contraception while using Skyrizi and for at least 20 weeks after the last Skyrizi dose. Talk to your doctor about your contraception options.

If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine. It is not known if Skyrizi passes into breast milk. You and your doctor should decide if you will breastfeed while using Skyrizi.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**How to take Skyrizi:**

- Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure how to use this medicine.
- Skyrizi is given as 2 injections under your skin (called “subcutaneous injections”).
- You and your doctor, pharmacist or nurse will decide if you should inject Skyrizi yourself. Do not inject yourself with this medicine unless you have been trained by your doctor, pharmacist or nurse. A caregiver may also give your injections after training. The AbbVie Care Support Program is also available to you if you require assistance with injections should you prefer nurse-administered injections. Information about the support services can be obtained by calling the AbbVie Care Support Program at 1-866-848-6472.
- **For a more comfortable injection:** Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **15 to 30 minutes** before injecting.
- Read the “**Instructions for Use**” before injecting Skyrizi yourself.

**Usual dose:**

The dose is 150 mg given as two 75 mg injections.

	<b>How much?</b>	<b>When?</b>
<b>1st dose</b>	150 mg ( <b>two</b> 75 mg injections)	When your doctor tells you
<b>2nd dose</b>	150 mg ( <b>two</b> 75 mg injections)	4 weeks after 1 <sup>st</sup> dose
<b>Further doses</b>	150 mg ( <b>two</b> 75 mg injections)	Every 12 weeks starting after 2 <sup>nd</sup> dose

Do not stop using Skyrizi without talking to your doctor first. If you stop treatment, your symptoms may come back.

**Overdose:**

If you think you, or a person you are caring for, have taken too much Skyrizi, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forgot to use Skyrizi, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. Talk to your doctor if you are not sure what to do.

**What are possible side effects from using Skyrizi?**

These are not all the possible side effects you may have when taking Skyrizi. If you experience any side effects not listed here, contact your doctor. Your doctor will decide if you can keep using Skyrizi.

Tell your doctor, pharmacist or nurse if you get any of the following side effects:

**Very common:** may affect more than 1 in 10 people

- upper respiratory infections with symptoms such as sore throat and stuffy nose

**Common:** may affect up to 1 in 10 people

- feeling tired
- fungal skin infection

- injection site reactions
- headache
- itching
- burning when you urinate or urinating more often than normal

**Uncommon:** may affect up to 1 in 100 people

- small raised red bumps on the skin

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
Serious Infections: Fever, flu-like symptoms, night sweats, cough, blood in your phlegm (mucus), warm, red or painful skin, muscle aches, weight loss		√	√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your doctor, pharmacist or nurse.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

Keep this medicine out of reach and sight of children.

Do not use this medicine after the expiration date which is stated on the syringe label and outer carton after 'EXP'.

Store in a refrigerator between 2 and 8 °C (36 and 46 °F). Do not freeze. Do not use if Skyrizi has been frozen.

Keep the pre-filled syringes in the original carton in order to protect from light.

The liquid should look clear to slightly yellow. The liquid may contain tiny white or clear particles. Do not use if liquid is cloudy or contains flakes or large particles.

This medicine is for single use only. Ask your doctor, pharmacist or nurse how to throw away used syringes safely.

**If you want more information about Skyrizi:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website ([www.abbvie.ca](http://www.abbvie.ca)), or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

Last Revised: APR 5, 2024



## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PrSKYRIZI®**

#### **90 mg/mL risankizumab injection, solution for subcutaneous injection in 90 mg/1 mL pre-filled syringe**

Read this carefully before you start taking Skyrizi. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Skyrizi.

#### **What is Skyrizi used for?**

Skyrizi is a prescription medicine used to treat adults with moderate to severe Crohn's disease, an inflammatory condition affecting the gastrointestinal tract that can cause abdominal pain, severe diarrhea, fatigue, and even weight loss.

#### **How does Skyrizi work?**

Skyrizi contains the active substance risankizumab. This medicine works by stopping a protein in the body called IL-23, which causes inflammation.

Skyrizi reduces the inflammation and can therefore help to reduce the signs and symptoms of your disease like abdominal pain, severe diarrhea, fatigue, and even weight loss.

If you have active Crohn's disease you may first be given other medicines. If these medicines do not work well enough, you will be given Skyrizi to treat your Crohn's disease.

#### **What are the ingredients in Skyrizi?**

Medicinal ingredients: risankizumab

Non-medicinal ingredients: disodium succinate hexahydrate, polysorbate 20, sorbitol, succinic acid, and water for injection.

#### **Skyrizi comes in the following dosage forms:**

Vial with 600 mg of risankizumab in 10 mL of solution for infusion (60 mg/mL). Skyrizi 60 mg/mL is a clear and colourless to slightly yellow liquid in a single-use vial. Each carton contains 1 vial.

Pre-filled cartridge with 360 mg of risankizumab in 2.4 mL of solution for subcutaneous injection (150 mg/mL). Skyrizi 150 mg/mL is a clear and colourless to yellow liquid in a pre-filled cartridge. Each carton contains 1 pre-filled cartridge with 1 on-body injector.

Pre-filled syringe with 90 mg of risankizumab in 1 mL of solution for injection (90 mg/mL). Skyrizi is a clear and colourless to slightly yellow liquid in a pre-filled syringe with needle guard. Each carton contains 4 pre-filled syringes.

**Do not use Skyrizi if:**

- You have had a serious allergic reaction to risankizumab or any of the other ingredients of Skyrizi (See **What are the ingredients in Skyrizi?**). Symptoms of serious allergic reactions include: trouble breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat.
- If any of these symptoms occur during treatment with Skyrizi, stop taking Skyrizi and get emergency medical help right away.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Skyrizi. Talk about any health conditions or problems you may have, including if you:**

- currently have an infection or if you have an infection that keeps coming back. Skyrizi may lower your ability to fight infections and may increase your risk of infections.
- have tuberculosis (TB) or have been in close contact with someone with TB.
- have recently received or plan to receive an immunization (vaccine). You should not be given certain types of vaccines (called 'live vaccines') while using Skyrizi.

**Talk to your healthcare professional right away if you have any of the symptoms of serious infection:**

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath
- cough
- blood in your phlegm (mucus)
- warm, red or painful skin, sores on your body different from your psoriasis, or a painful skin rash with blisters
- muscle aches
- weight loss

**Talk to your healthcare professional right away if you have any of the symptoms of an allergic reaction, including:**

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

**Other warnings you should know about:**

Skyrizi is not approved for children and adolescents with Crohn's disease under 18 years of age. This is because it has not been studied in this age group.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This is because it is not known if Skyrizi can harm your unborn baby. If you are a woman of childbearing potential, use adequate contraception while using Skyrizi and for at least 20 weeks after the last Skyrizi dose. Talk to your doctor about your contraception options.

If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine. It is not known if Skyrizi passes into breast milk. You and your doctor should decide if you will breastfeed while using Skyrizi.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**How to take Skyrizi:**

**Usual dose:**

You will begin treatment with Skyrizi with a starting dose which will be given to you by a qualified healthcare professional intravenously (through a vein) over at least 60 minutes.

**Starting doses**

	<b>How much?</b>	<b>When?</b>
Starting doses	600 mg	When your doctor tells you
	600 mg	4 weeks after 1 <sup>st</sup> dose
	600 mg	4 weeks after 2 <sup>nd</sup> dose

Afterwards, you will receive a different dose of Skyrizi as maintenance therapy by an injection under your skin (subcutaneous injection) using the 90 mg/1 mL (90 mg/mL) pre-filled syringes.

A healthcare professional must administer four 90 mg/1 mL (90 mg/mL) single-dose syringes to achieve the full 360 mg maintenance dose.

**Maintenance doses**

	<b>How much?</b>	<b>When?</b>
<b>1<sup>st</sup> maintenance dose</b>	360 mg ( <b>four</b> 90 mg injections)	4 weeks after the last starting dose (at Week 12)
<b>Further doses</b>	360 mg ( <b>four</b> 90 mg injections)	Every 8 weeks, starting after the 1 <sup>st</sup> maintenance dose

**Overdose:**

If you think you, or a person you are caring for, have taken too much Skyrizi, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget or miss the appointment for any of your doses, contact your doctor to reschedule your appointment as soon as you remember.

Do not stop using Skyrizi without talking to your doctor first. If you stop treatment, your symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

**What are possible side effects from using Skyrizi?**

These are not all the possible side effects you may have when taking Skyrizi. If you experience any side effects not listed here, contact your doctor. Your doctor will decide if you can keep using Skyrizi.

Tell your doctor, pharmacist or nurse if you get any of the following side effects:

**Very common:** may affect more than 1 in 10 people

- upper respiratory infections with symptoms such as sore throat and stuffy nose

**Common:** may affect up to 1 in 10 people

- feeling tired
- fungal skin infection
- injection site reactions
- headache
- itching
- burning when you urinate or urinating more often than normal

**Uncommon:** may affect up to 1 in 100 people

- small raised red bumps on the skin

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
Serious Infections: Fever, flu-like symptoms, night sweats, cough, blood in your phlegm (mucus), warm, red or painful skin, muscle aches, weight loss		√	√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your doctor, pharmacist or nurse.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage (instructions for healthcare professionals only):

Skyrizi 90 mg/1 mL (90 mg/mL) pre-filled syringe is given in a hospital or clinic and patients should not need to store or handle it.

Keep this medicine out of reach and sight of children.

Do not use this medicine after the expiration date which is stated on the syringe label and outer carton after 'EXP'.

Store in a refrigerator between 2 and 8 °C (36 and 46 °F). Do not freeze. Do not use if Skyrizi has been frozen.

Keep the pre-filled syringes in the original carton in order to protect from light.

The liquid should look clear to slightly yellow. The liquid may contain tiny white or clear particles. Do not use if liquid is cloudy or contains flakes or large particles.

This medicine is for single use only.

**The following information is intended for healthcare professionals only**

Instructions for use when using the 90 mg/1 mL (90 mg/mL) pre-filled syringes

1. This medicinal product should be prepared and administered by a healthcare professional.
2. Administer each pre-filled syringe subcutaneously.
3. Before injecting, remove the carton from the refrigerator and without removing the pre-filled syringes from the carton. Allow Skyrizi to reach room temperature out of direct sunlight (15 to 30 minutes).
4. Visually inspect the solution for foreign particulate matter and discoloration. Do not use this medicinal product if the solution is cloudy or discolored or contains large particles.
5. Use **four** 90 mg pre-filled syringes to administer the maintenance dose of 360 mg subcutaneously as follows:
  - Inject one pre-filled syringe after the other in different anatomic locations (such as thighs or abdomen).
  - Do not inject into areas where the skin is tender, bruised, erythematous, indurated or affected by any lesions.
6. If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing at the regular scheduled time.
7. Do not use this medicinal product if the carton seal is broken or missing, or if any of the components are damaged.

**If you want more information about Skyrizi:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website ([www.abbvie.ca](http://www.abbvie.ca)), or by calling 1-888-704-8271.

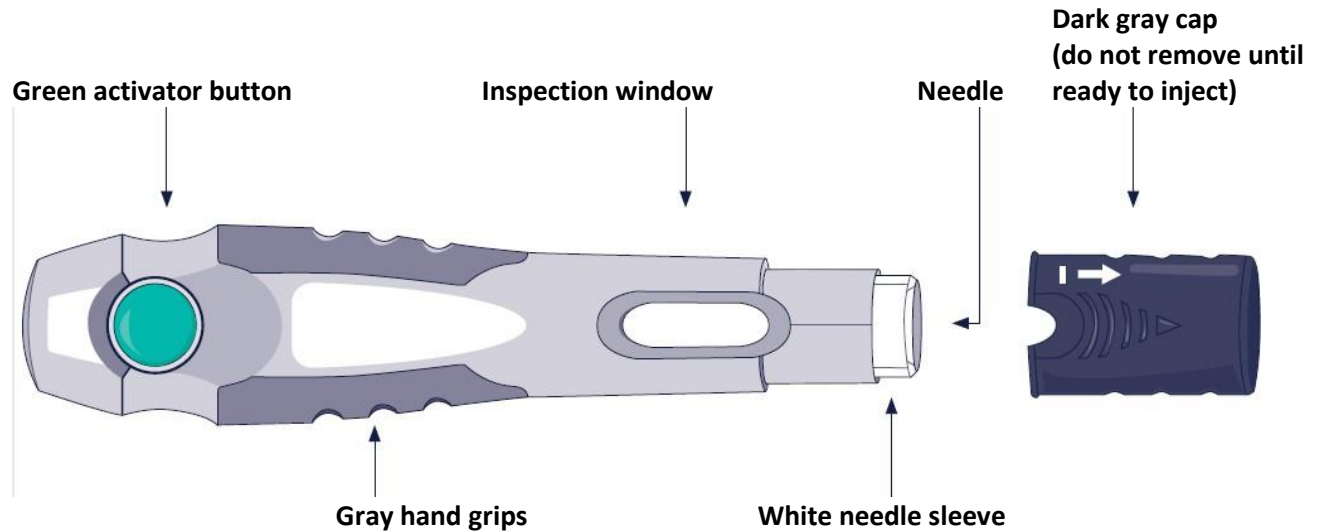
This leaflet was prepared by AbbVie Corporation.

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**Instructions for Use**  
**Skyrizi®**  
(risankizumab injection)  
150 mg in 1 mL sterile solution (150 mg/mL) subcutaneous injection  
Pre-filled pen

**Please read complete instructions before using Skyrizi.**

**Skyrizi pre-filled pen**



**Important information to know before you inject Skyrizi**

- Receive training on how to inject Skyrizi before giving an injection. Talk to your doctor, pharmacist or nurse if you need help. The AbbVie Care Support Program is also available to you if you have questions regarding the injection process. Information about the support services can be obtained by calling the AbbVie Care Support Program at 1-866-848-6472.
- Mark the dates on your calendar so you know when to next use Skyrizi.
- Keep Skyrizi in the original carton to protect from light until it is time to use it.
- Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **30 to 90 minutes** before injecting.
- **Do not** inject if the liquid in the inspection window is cloudy or contains flakes or large particles. The liquid should look clear to yellow and may contain tiny white or clear particles.
- **Do not** use if expiration date (EXP) has passed.
- **Do not** use if liquid has been frozen (even if thawed).
- **Do not** shake the pen.
- **Do not** use if pen has been dropped or damaged.
- **Do not** use if the carton perforations are broken. Return this medicine to the pharmacy.
- **Do not** remove the dark gray cap until just before the injection.

## Storage Information

Store in refrigerator between 2 and 8 °C (36 and 46 °F). Do not freeze. Keep Skyrizi out of reach and sight of children. Keep Skyrizi pre-filled pen in the original carton to protect from light.

Skyrizi 150 mg/mL pre-filled pen may be stored out of the refrigerator (up to a maximum of 25°C [77°F]) for up to 24 hours in the original carton to protect from light.

## Follow the steps below each time you use Skyrizi

### Prepare for Injection

#### STEP 1



Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **30 to 90 minutes** before injecting.

- **Do not** remove the pen from the carton while allowing Skyrizi to reach room temperature.
- **Do not** warm Skyrizi in any other way. For example, do not warm it in a microwave or in hot water.
- **Do not** use the pen if liquid has been frozen, even if it has been thawed.

#### STEP 2



You will need these supplies:

- 1 pre-filled pen

Not provided in the Skyrizi carton:

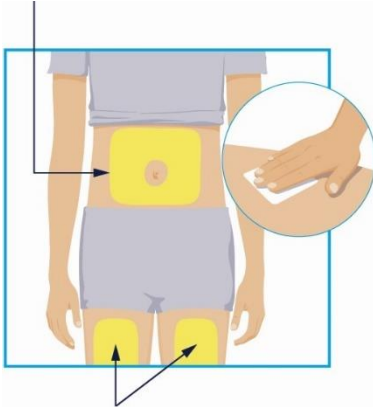
- 1 alcohol pad
- 1 cotton ball or gauze pad
- special disposal container

Place these items on a clean, flat surface.

Wash and dry your hands.

#### STEP 3

#### Areas to inject



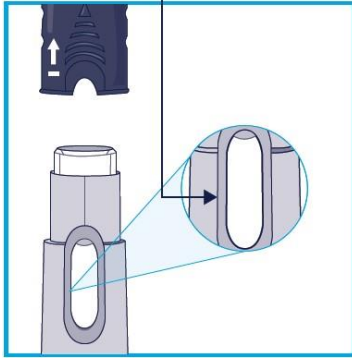
Areas to inject

Choose from these 3 areas to inject:

- front of left thigh or right thigh
- belly (abdomen) at least 5 cm (2 inches) from the belly button (navel)

Before the injection, wipe where you will inject in a circular motion with an alcohol pad.

- **Do not** touch or blow on the injection site after it is cleaned. Allow the skin to dry before injecting.
- **Do not** inject through clothes.
- **Do not** inject into skin that is sore, bruised, red, hard, scarred, or has stretch marks.
- **Do not** inject into areas affected by psoriasis.

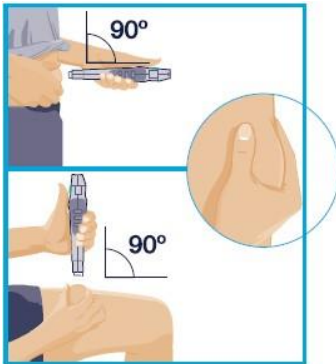
**STEP 4****Check liquid**

Hold the pen with the dark gray cap pointing up, as shown.

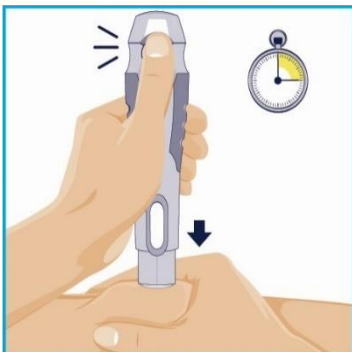
- Pull the dark gray cap straight off.
- Throw the dark gray cap away.

Check the liquid through the inspection window.

- It is normal to see bubbles in the liquid.
- The liquid should look clear to yellow and may contain tiny white or clear particles.
- **Do not** use if the liquid is cloudy or contains flakes or large particles.

**STEP 5****Abdomen or Thigh**

- Hold the pen with your fingers on the gray hand grips.
- Turn the pen so that the white needle sleeve points toward the injection site and you can see the green activator button.
- Gently squeeze the skin at your injection site to make a raised area and hold it firmly.
- Place the white needle sleeve straight (90° angle) against the raised injection site.

**Inject Skyrizi****STEP 6****First “click” 15 seconds**

Hold the pen so that you can see the green activator button and inspection window.

Push and keep pressing the pen down against the raised injection site.

- The pen will activate only if the white needle sleeve is pressed down against the injection site before pressing the green activator button.

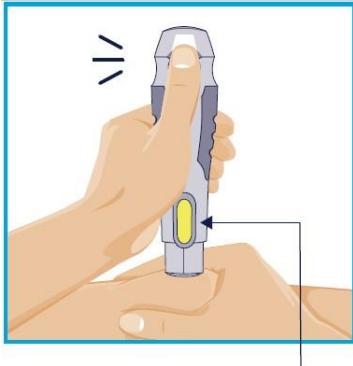
Press the green activator button and hold the pen for **15** seconds.

- A loud “click” means the start of the injection.



**STEP 7**

**Second “click”**



**Yellow indicator**

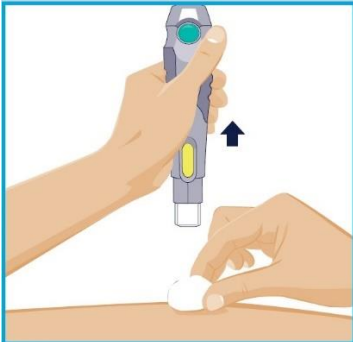
Keep pressing the pen down against the injection site.

The injection is complete when:

- the pen has made a second “click” or
- the yellow indicator has filled the inspection window.

This takes **up to 15** seconds.

**STEP 8**



When the injection is complete, slowly pull the pen out from the skin.

The white needle sleeve will cover the needle tip and make another “click.”

After completing the injection, place a cotton ball or gauze pad on the skin at the injection site.

- **Do not** rub the injection site.
- Slight bleeding at the injection site is normal.

**After your Injection**

**STEP 9**



Throw away the used pen in a special disposal container right away after use.

- **Do not** throw away the used pen in the household waste.
- Your doctor, pharmacist or nurse will tell you how to return the full special disposal container.

**Need Help?**

Call your doctor to talk about any questions you may have. For questions or concerns visit the manufacturer’s website ([www.abbvie.ca](http://www.abbvie.ca)) or call 1-888-704-8271.

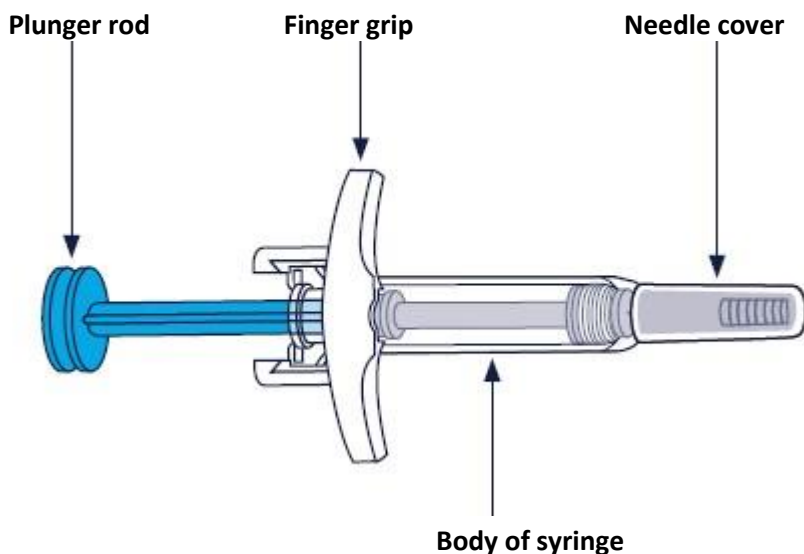
This leaflet was prepared by AbbVie Corporation.

Last Revised: APR 5, 2024

**Instructions for Use**  
**Skyrizi®**  
(risankizumab injection)  
150 mg in 1 mL sterile solution (150 mg/mL) subcutaneous injection  
Pre-filled syringe

**Please read complete instructions before using Skyrizi.**

**Skyrizi pre-filled syringe**



**Important information to know before you inject Skyrizi**

- If your doctor decides that you or a caregiver may be able to give your injections at home, you and your caregiver should receive training on how to inject Skyrizi before giving an injection. Injections should be given in the thighs or abdomen. Caregivers can also give Skyrizi in the upper outer arm. Talk to your doctor, pharmacist or nurse if you need help. The AbbVie Care Support Program is also available to you if you require assistance with injections should you prefer nurse-administered injections. Information about the support services can be obtained by calling the AbbVie Care Support Program at 1-866-848-6472.
- Mark the dates on your calendar so you know when to next use Skyrizi.
- Keep Skyrizi in the original carton to protect from light until it is time to use it.
- **Do not** inject if the liquid is cloudy or contains flakes or large particles. The liquid should look clear to yellow and may contain tiny white or clear particles.
- **Do not** use if the expiry date (EXP) has passed.
- **Do not** use if the liquid has been frozen (even if thawed).
- **Do not** shake the syringe.
- **Do not** use if the syringe has been dropped or damaged.
- **Do not** use if the carton perforations are broken. Return this medicine to the pharmacy.
- **Do not** remove the needle cover until just before the injection.

**For a more comfortable injection:** Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **15 to 30 minutes** before injecting.

- **Do not** remove the syringe from the carton until ready to inject.
- **Do not** warm Skyrizi in any other way. For example, **do not** warm it in a microwave or in hot water.

### Storage Information

Store in refrigerator between 2 and 8 °C (36 and 46 °F). Do not freeze. Keep Skyrizi out of reach and sight of children. Keep Skyrizi pre-filled syringe in the original carton to protect from light.

Skyrizi 150 mg/mL pre-filled syringe may be stored out of the refrigerator (up to a maximum of 25°C [77°F]) for up to 24 hours in the original carton to protect from light.

### Follow the steps below each time you use Skyrizi

#### Prepare for Injection

##### STEP 1



You will need these supplies:

- 1 pre-filled syringe – remove it from the cardboard sleeve by holding the finger grip. **Do not** hold or pull plunger rod when removing the pre-filled syringe from the sleeve.

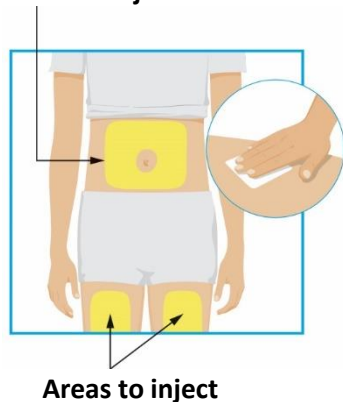
Not provided in the Skyrizi carton:

- 1 alcohol pad
- 1 cotton ball or gauze pad
- special disposal container

Place these items on a clean, flat surface.  
Wash and dry your hands.

##### STEP 2

##### Areas to inject

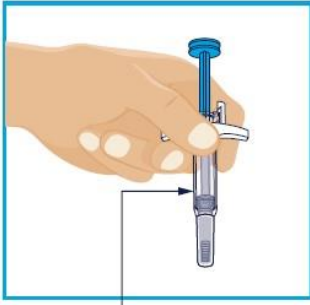


Choose from these 3 areas to inject:

- front of left thigh or right thigh
- belly (abdomen) at least 5 cm (2 inches) from the belly button (navel)

Before the injection, wipe where you will inject in a circular motion with an alcohol pad.

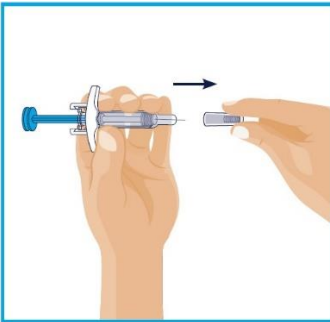
- **Do not** touch or blow on the injection site after it is cleaned. Allow the skin to dry before injecting.
- **Do not** inject through clothes.
- **Do not** inject into skin that is sore, bruised, red, hard, scarred, or has stretch marks.
- **Do not** inject into areas affected by psoriasis.

**STEP 3****Check liquid**

Hold the syringe with covered needle pointing down, as shown.

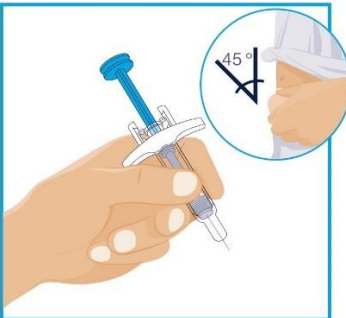
Check the liquid in the syringe.

- It is normal to see bubbles in the window.
- The liquid should look clear to yellow and may contain tiny white or clear particles.
- **Do not** use if the liquid is cloudy or contains flakes or large particles.

**STEP 4**

Removing the needle cover:

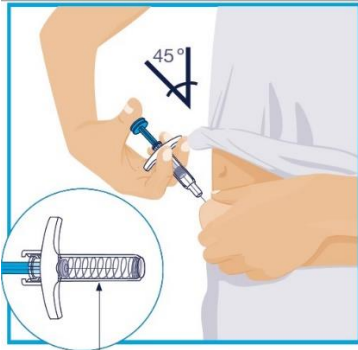
- Hold the syringe in one hand between the finger grip and needle cover.
- With the other hand, gently pull the needle cover straight off.
- **Do not** hold or pull plunger rod when removing the needle cover.
- You may see a drop of liquid at the end of the needle. This is normal.
- Throw away the needle cover.
- **Do not** touch the needle with your fingers or let the needle touch anything.

**Inject Skyrizi****STEP 5**

Hold the body of the syringe in one hand between the thumb and index finger, like you would a pencil.

Gently pinch the area of cleaned skin with your other hand and hold it firmly.

Insert the needle all the way into the skin at about a 45-degree angle using a quick, short movement. Keep the syringe steady at the same angle.

**STEP 6****Needle guard**

Slowly push the plunger rod all the way in until all of the liquid is injected.

Pull the needle out of the skin while keeping the syringe at the same angle.

Slowly take your thumb off the plunger rod. The needle will then be covered by the needle guard.

- The needle guard will not activate unless all the liquid is injected.
- Speak to your doctor, pharmacist or nurse if you think you have not given a full dose.

Press a cotton ball or gauze pad where you have injected and hold for 10 seconds.

**Do not** rub the skin where you have injected. You may have slight bleeding from where you injected. This is normal.

**After injection****STEP 7**

Throw away the used syringe in a special disposal container right away after use.

- **Do not** throw away the used syringe in the household waste.
- Your doctor, pharmacist or nurse will tell you how to return the full special disposal container.

**Need Help?**

Call your doctor to talk about any questions you may have. For questions or concerns visit the manufacturer's website ([www.abbvie.ca](http://www.abbvie.ca)) or call 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

Last Revised: APR 5, 2024

## Instructions for Use Skyrizi®

(risankizumab injection)

360 mg in 2.4 mL sterile solution (150 mg/mL) for subcutaneous injection

On-body injector with pre-filled cartridge

**Please read complete instructions before using Skyrizi.**

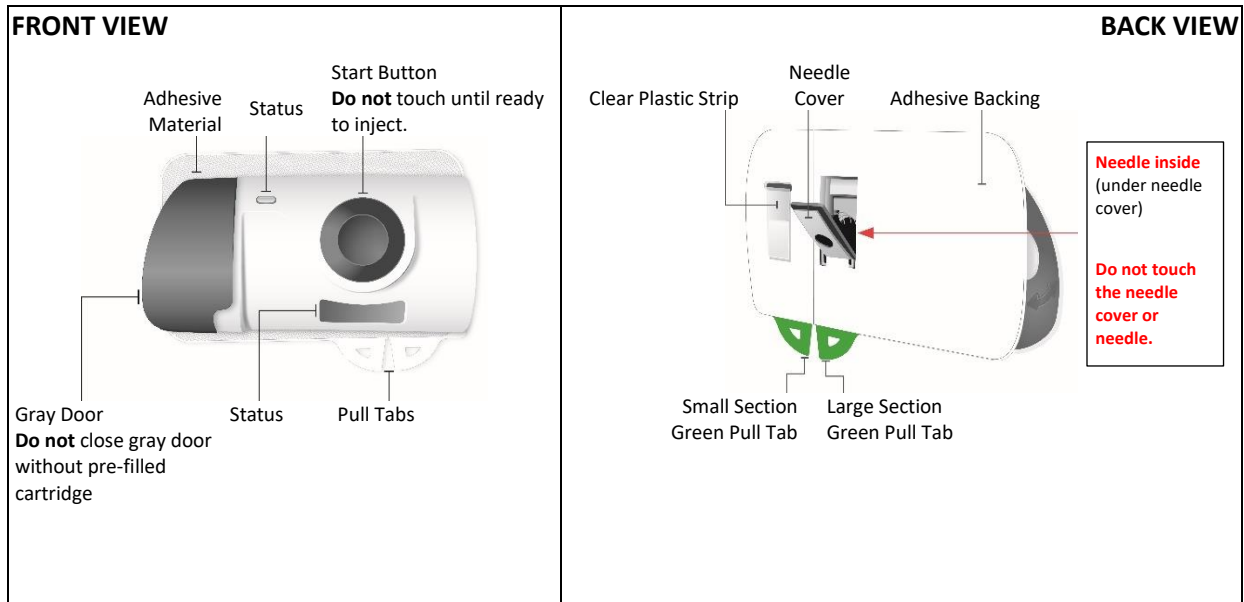
### Important information to know before you inject Skyrizi

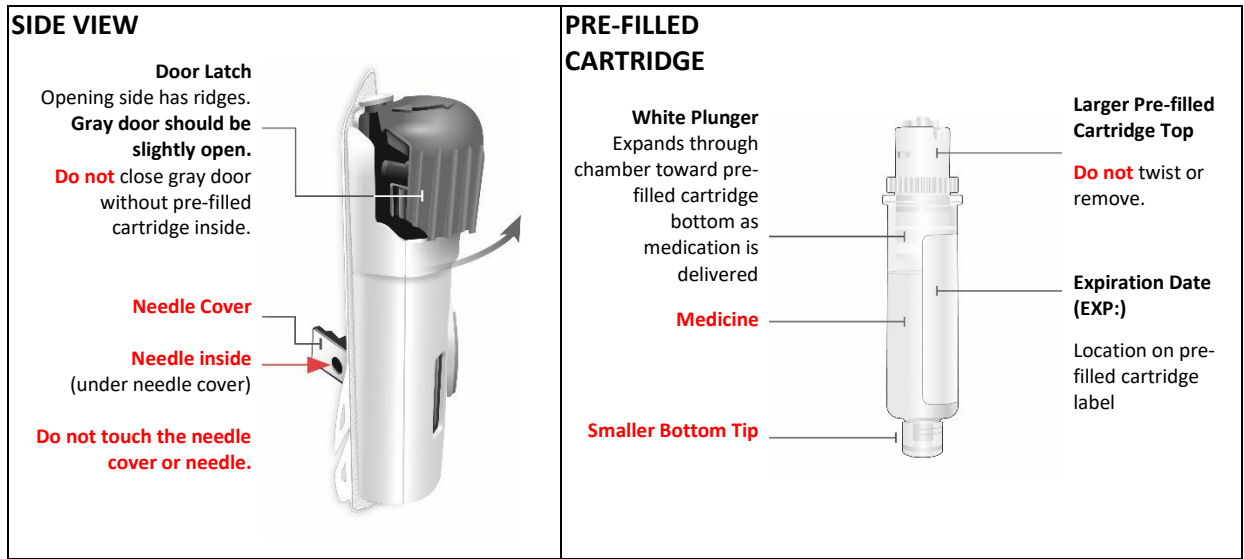
- Receive training on how to inject Skyrizi before giving an injection. Talk to your doctor, pharmacist or nurse if you need help. The AbbVie Care Support Program is also available to you if you have questions regarding the injection process. Information about the support services can be obtained by calling the AbbVie Care Support Program at 1-866-848-6472.
- Mark the dates on your calendar so you know when to next use Skyrizi.
- **Do not** shake the Skyrizi carton, on-body injector or pre-filled cartridge.
- **Do not** reuse on-body injector or pre-filled cartridge. The on-body injector and pre-filled cartridge are for 1-time (single-dose) use only. This single-dose on-body injector is designed for use with Skyrizi pre-filled cartridge only.
- **Do not** let the on-body injector get wet with water or any other liquids.
- Physical activity should be limited during the injection process. Moderate physical activities can be done, such as walking, reaching and bending.
- The on-body injector and the pre-filled cartridge are not made with natural rubber latex.

### Storage Information

- Store in refrigerator between 2 and 8 °C (36 and 46 °F). Do not freeze. Keep Skyrizi out of reach and sight of children. Keep Skyrizi in the original carton to protect from light and physical damage until time to use.

### Get to know your Skyrizi on-body injector and pre-filled cartridge

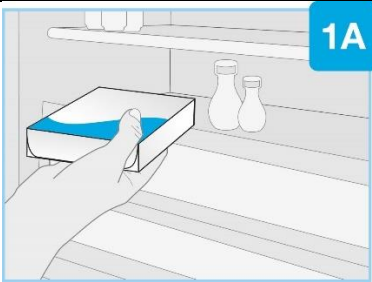




Follow the steps below each time you use Skyrizi

**Prepare for Injection**

**STEP 1 – Get Ready**

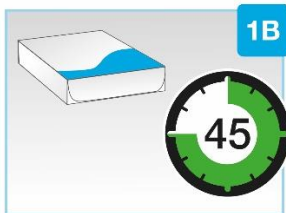


Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **45 to 90 minutes** before injecting.

Check expiration date (EXP) on the carton. Do not use Skyrizi if the expiration date (EXP) has passed.

**Do not** remove the cartridge or on-body injector from the carton while allowing Skyrizi to reach room temperature.

**Do not** warm Skyrizi in any other way. For example, do not warm it in a microwave or in hot water.



**Wait at least 45 minutes.**

**Open the carton and remove the plastic tray.**

Lift up the flap on the side of the carton.

Take out the plastic tray.

## Sharps Container



## Gather all supplies and wash your hands

You will need these supplies:

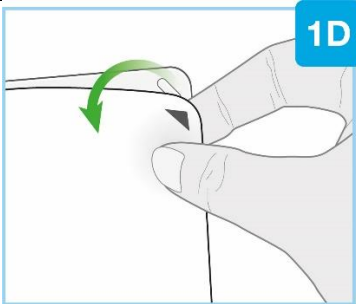
- Plastic tray containing 1 on-body injector and 1 pre-filled cartridge

Not provided in the Skyrizi carton:

- alcohol pads
- 1 cotton ball or gauze pad
- special disposal container

Place these items on a clean, flat surface.

Wash and dry your hands.

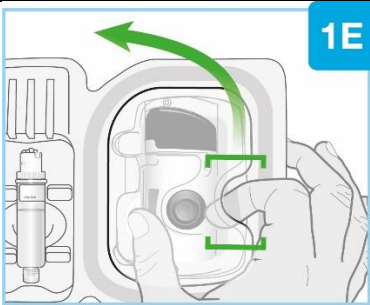


## Remove the white paper tray seal

Locate the black arrow.

Peel away the white paper tray seal from the plastic tray.

**Do not** use the on-body injector and pre-filled cartridge if the white paper tray seal is missing or damaged and return the carton to the pharmacy.



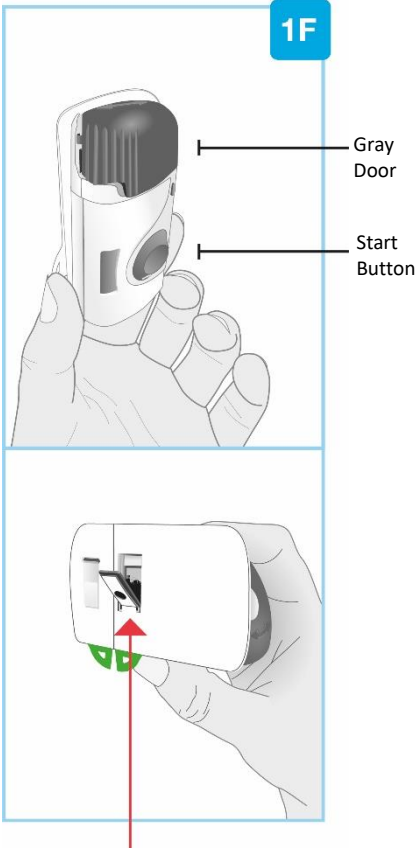
## Lift the plastic cover

Locate the rounded opening on the top cover.

Insert your index finger in the opening and place your thumb on the opposite side.

Lift the cover to remove and set aside.





1F

Gray Door

Start Button

**Needle inside**  
(under needle cover)

### Inspect the on-body injector

Check that the on-body injector is intact and undamaged.

The gray door should be slightly open.

If the gray door does not open, press in firmly on the gray door ridges (left side of door) and swing open the door.

**Do not** close the gray door before the pre-filled cartridge is loaded.

**Do not** use on-body injector if you drop it, discover missing pieces, or it is damaged.

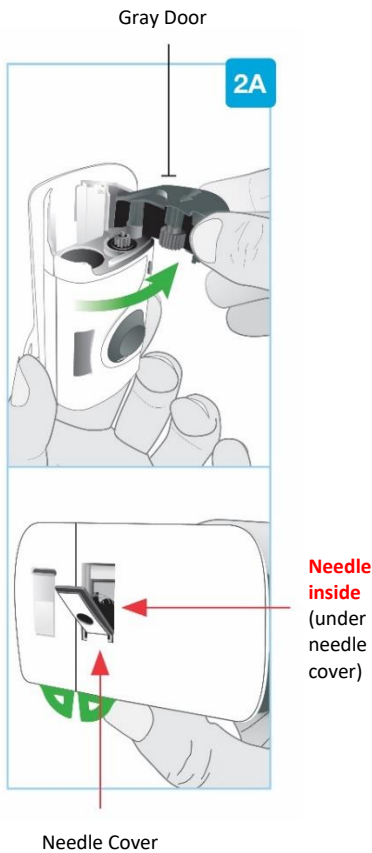
**Do not** touch the gray start button until it is time to inject. It can be pressed **1** time only.

If the gray start button is pressed before placing it on your body, the on-body injector can no longer be used. If this happens, speak to your doctor, pharmacist or nurse.

**Do not** touch the needle cover or the needle.

Proceed to Set up on-body injector.

## STEP 2 - Set up on-body injector



### Fully open the grey door:

Avoid touching the needle cover area on the back of the on-body injector. The needle is behind the needle cover.

Swing the grey door all the way to the right to open it.

If the grey door does not open, press in firmly on the grey door ridges (left side of door) and swing open the door.

**Do not** close the grey door before the pre-filled cartridge is loaded.

Put the on-body injector aside on a clean surface.



### Inspect the pre-filled cartridge

Carefully remove the pre-filled cartridge from the plastic tray.

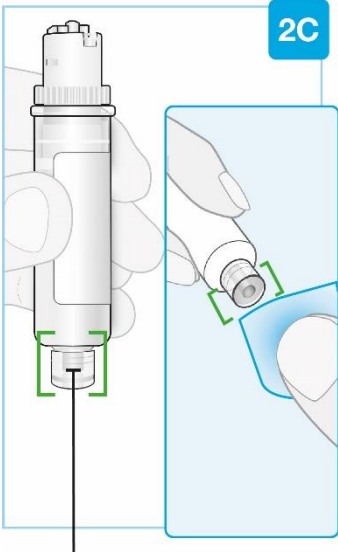
**Do not** twist or remove cartridge top.

Check the pre-filled cartridge:

- The liquid should look clear to yellow and may contain tiny white or clear particles. It is normal to see one or more bubbles.
- **Do not** use if the liquid is cloudy, discoloured, or contains flakes or large particles.
- The pre-filled cartridge parts and the clear plastic are not cracked or broken.

**Do not** use if the liquid has been frozen (even if thawed).

**Do not** use the pre-filled cartridge if you drop it, discover missing pieces, or it is damaged.



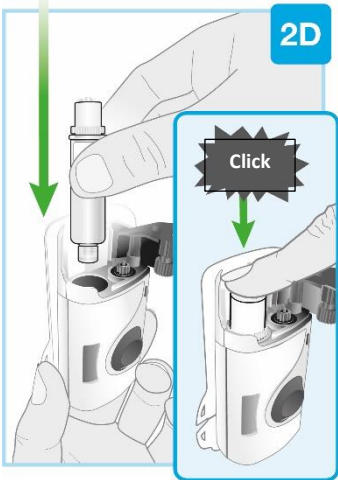
**Smaller Bottom Tip**      **Clean center of smaller bottom tip**

**Clean the smaller bottom tip of the pre-filled cartridge**

Locate the smaller bottom tip of the pre-filled cartridge.  
Clean smaller bottom tip of the pre-filled cartridge with an alcohol pad. Make sure to use the alcohol pad to clean the center of the smaller bottom tip of the pre-filled cartridge.

**Do not** touch the smaller bottom tip of the pre-filled cartridge after cleaning.

Insert straight



**Load the cleaned pre-filled cartridge into the on-body injector**

**Do not** twist or remove the pre-filled cartridge top.

Insert the smaller bottom tip of the pre-filled cartridge into the on-body injector first.

Firmly push down on the pre-filled cartridge top until you hear a "click".

After loading the pre-filled cartridge, you may see a few drops of medicine on the back of the on-body injector. This is normal.

Make sure to proceed to the next step without delay. Waiting will dry out the medicine and the on-body injector will not work afterwards.



**Close the grey door:**

Swing the grey door to the left, then squeeze firmly and listen for the grey door to "snap" shut.

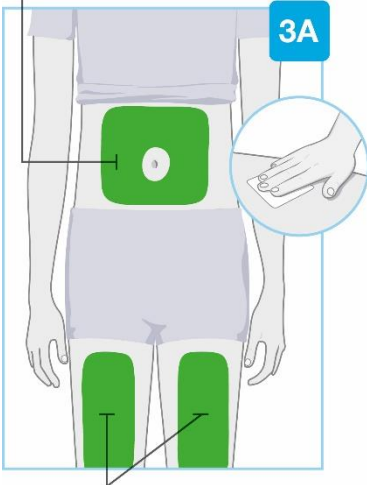
The grey door should stay locked after loading the pre-filled cartridge.

**Do not** close the grey door if the pre-filled cartridge is not fully inserted or is missing.

Proceed without delay to the next step.

### STEP 3 - Prepare to inject

#### Areas to inject



Areas to inject

#### Pick your injection area

Choose from these 3 areas to inject:

- front of left thigh or right thigh
- belly (abdomen) at least 5 cm (2 inches) from the belly button (navel)

**Do not** inject into areas of the skin that naturally fold or bulge because the on-body injector could fall off during wear.

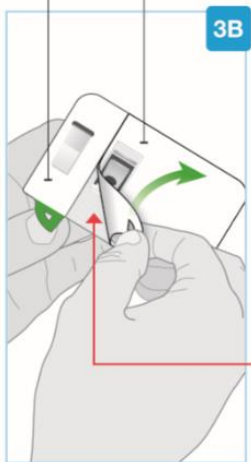
**Do not** inject into skin that is sore, bruised, red, hard, scarred, or has stretch marks, moles or excessive hair. You can trim the excessive hair from the injection area.

**Do not** inject through clothes.

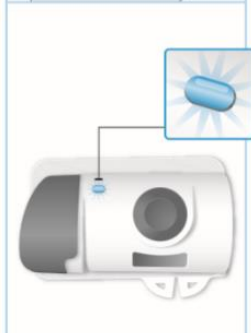
Before the injection, wipe where you will inject in a circular motion with an alcohol pad.

**Do not** touch or blow on the injection site after it is cleaned. Allow the skin to dry before placing the on-body injector on the body.

Small Section Large Section



Needle inside  
(under cover  
needle)



#### Peel both tabs to expose skin adhesive

Turn the on-body injector over to find both green pull tabs.

Avoid touching the needle cover (needle inside).

Peel away the **large section** using the green pull tab to expose the skin adhesive.

Peel away the **small section** using the green pull tab to expose the skin adhesive. This will remove the clear plastic strip, activating the on-body injector.

Check the status light when the on-body injector beeps.

The status light will flash blue when the on-body injector is activated.


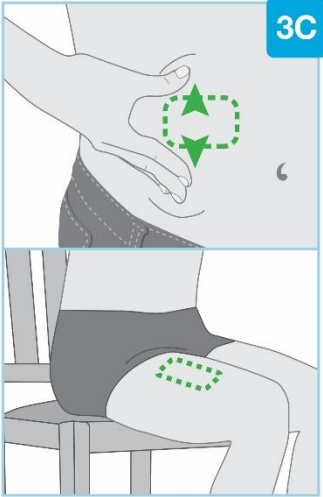
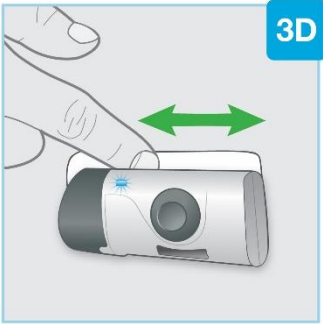
If the status light does not flash blue, speak to your doctor, pharmacist, nurse or AbbVie Care Support Program.

**Do not** press the grey start button yet.

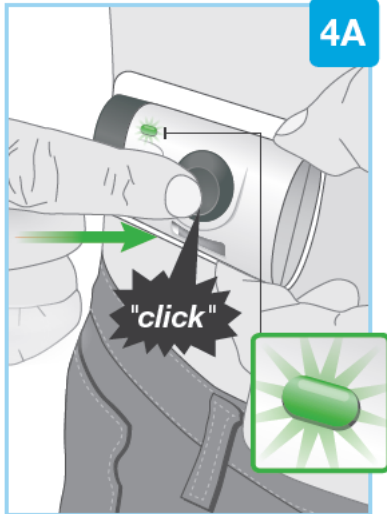
**Do not** touch the needle cover or the needle.

**Do not** pull the adhesive material off on-body injector or allow the sticky side to fold and stick to itself.

The Skyrizi on-body injector must be placed on the skin and injection must be started within 30 minutes after removing

	<p>the green pull tabs or it will not work. Make sure to proceed to next step without delay.</p>
	<p><b>If the status light flashes red, the on-body injector is not working properly. Do not continue to use it.</b></p> <p>Speak to your doctor, pharmacist, nurse or AbbVie Care Support Program for assistance.</p> <p>If on-body injector is attached to your body, carefully remove from your skin.</p>
	<p><b>Prepare the on-body injector for placement</b></p> <p>For the belly, move and hold the skin to create a firm, flat surface for injection at least 5 cm from your belly button (navel). Make sure to sit up straight to avoid skin folds and bulges.</p> <p>You do not need to pull the skin flat for the front of left thigh or right thigh.</p> <p>Make sure to place the on-body injector so that you can see the blue status light.</p>
	<p><b>Place the on-body injector on your skin</b></p> <p>When the blue light flashes, the on-body injector is ready. Place the on-body injector onto the cleaned skin with the status light visible.</p> <p><b>Do not</b> place the on-body injector on clothes. Only place on bare skin.</p> <p>Run your finger around the adhesive material to secure it.</p> <p><b>Do not</b> move or adjust the on-body injector after it has been placed on your skin.</p> <p>Proceed without delay to the next step.</p>

## STEP 4 - Inject Skyrizi

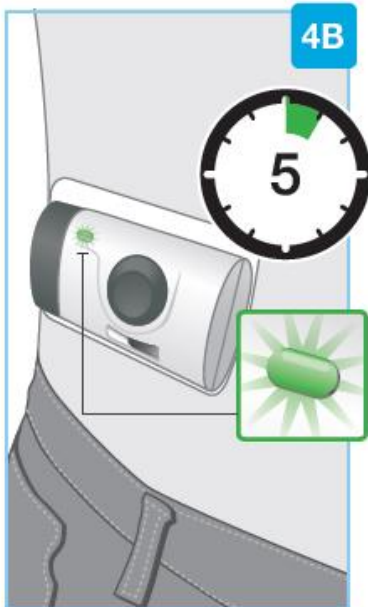


### Start injection

Firmly press and release the grey start button.

- You will hear a "click" and may feel a needle pinch.
- Check the status light when the on-body injector beeps.
- After starting the injection, the status light will continuously flash green.
- After starting the injection, you will hear pumping sounds as the on-body injector delivers the medicine.

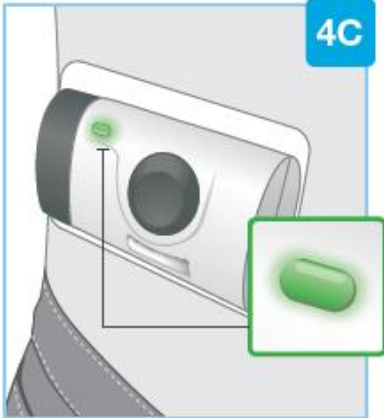
**Do not** continue to use the on-body injector if status light flashes red. Carefully remove from skin if the status light flashes red. If this happens, speak to your doctor, pharmacist, nurse, or AbbVie Care Support Program.



### Wait for the injection to finish

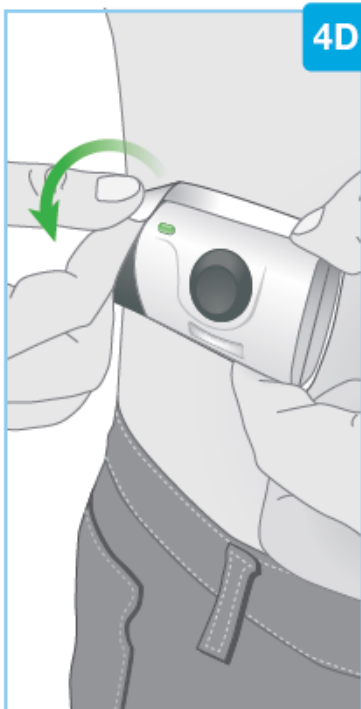
- It may take up to 5 minutes to complete the full dose of medicine. The on-body injector will automatically stop when the injection is finished.
- During the injection, the status light will continue to flash green.
- During the injection, you will hear pumping sounds as the on-body injector continues delivering the medicine.
- During the injection, moderate physical activities can be done, such as walking, reaching and bending.

**Do not** continue to use the on-body injector if the status light flashes red. Carefully remove it from the skin if the status light flashes red. If this happens, speak to your doctor, pharmacist, nurse, or AbbVie Care Support Program.



**Injection is complete when:**

- the on-body injector stops on its own
- you hear a beep and the status light changes to solid green. If the status light has changed to solid green, this means that the injection is complete.



**Remove the on-body injector:**

**Do not** put your fingers on the back side of the on-body injector when removing it from your skin.

When the injection is done, grab the corner of the adhesive to carefully peel the on-body injector from the skin.

Avoid touching the needle cover or needle on the back of the on-body injector.

After removing the on-body injector, you will hear several beeps and the status light will turn off.

The needle cover will cover the needle when the on-body injector is removed from the skin.

It is normal to see a few small drops of liquid on your skin after removing the on-body injector.

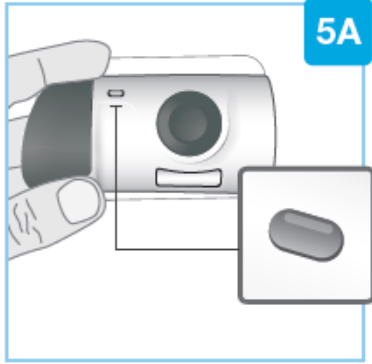
Press a cotton ball or gauze pad over the injection site on your skin and hold for 10 seconds.

**Do not** rub the injection site.

Slight bleeding at the injection site is normal.

Proceed to the next step.

## Step 5 - After your Injection

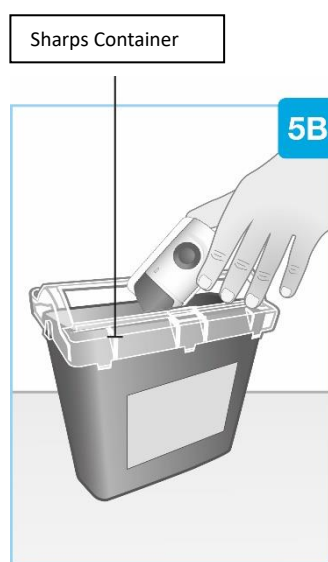


### Check the on-body injector

Inspect the medicine window and status light.

Check to see that the white plunger fills the entire medicine window and the solid green light turns off, letting you know that all the medicine has been injected.

- If the white plunger does not fill the window, speak to your doctor, pharmacist or nurse.








### Disposal

Throw away the used on-body injector in a special disposal container straight after use.

- The on-body injector contains batteries, electronics, and a needle.
- Leave the pre-filled cartridge in the on-body injector.
- **Do not** throw away the used on-body injector in the household waste.
- Your doctor, pharmacist, nurse, or AbbVie Care Support Program will tell you how to return the full special disposal container. There may be local guidelines for disposal.



Symbol Key		
	Flashing blue light	On/ Ready
	Flashing green light	Injection has started
	Solid green light	Injection has finished
	No light	Off/ Finished
	Flashing red light	<b>Do not</b> continue to use the on-body injector. It is not working properly. Call AbbVie Care Support Program at 1-866-848-6472 for more information.

**Need Help?**

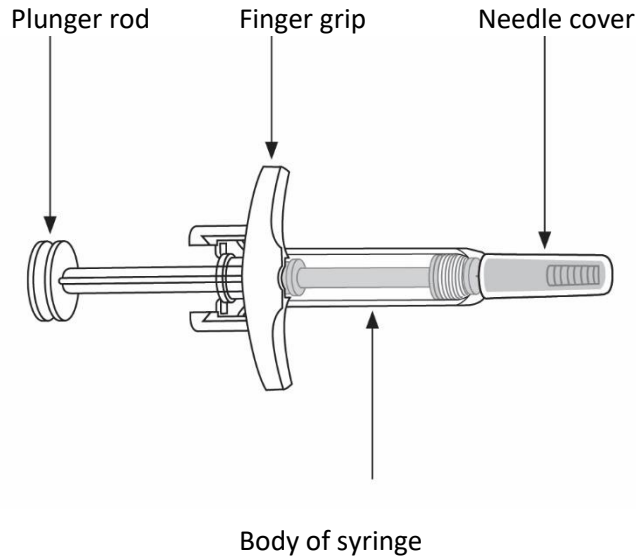
Call your doctor to talk about any questions you may have. For questions or concerns visit the manufacturer’s website ([www.abbvie.ca](http://www.abbvie.ca)) or call 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

Last Revised: APR 5, 2024

**Instructions for Use**  
**Skyrizi®**  
(risankizumab injection)  
75 mg in 0.83 mL sterile solution (90 mg/mL) subcutaneous injection  
Pre-filled syringe

**Please read complete instructions before using Skyrizi.**



**Important information to know before you inject Skyrizi**

- If your doctor decides that you or a caregiver may be able to give your injections at home, you and your caregiver should receive training on how to inject Skyrizi before giving an injection. Injections should be given in the thighs or abdomen. Caregivers can also give Skyrizi in the upper outer arm. Talk to your doctor, pharmacist or nurse if you need help. The AbbVie Care Support Program is also available to you if you require assistance with injections should you prefer nurse-administered injections. Information about the support services can be obtained by calling the AbbVie Care Support Program at 1-866-848-6472.
- Mark the dates on your calendar so you know when to next use Skyrizi.
- Keep Skyrizi in the original carton to protect from light until it is time to use it.
- **Do not** inject if the liquid is cloudy or contains flakes or large particles. The liquid should look clear to slightly yellow and may contain tiny white or clear particles.
- **Do not** use if the expiry date (EXP) has passed.
- **Do not** use if the liquid has been frozen (even if thawed).
- **Do not** shake the syringe.
- **Do not** use if the syringe has been dropped or damaged.
- **Do not** use if the syringe tray cover is broken or missing. Return this medicine to the pharmacy.
- **Do not** remove the needle cover until just before the injection.

**For a more comfortable injection:** Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **15 to 30 minutes** before injecting.

- **Do not** remove the syringes from the carton until ready to inject.
- **Do not** warm Skyrizi in any other way. For example, **do not** warm it in a microwave or in hot water.

### Storage Information

Store in refrigerator between 2 and 8 °C (36 and 46 °F). Do not freeze. Keep Skyrizi out of reach and sight of children. Keep Skyrizi pre-filled syringe in the original carton to protect from light.

### Follow the steps below each time you use Skyrizi

#### Prepare for Injection

##### STEP 1



You will need these supplies:

- 2 pre-filled syringes

Not provided in the Skyrizi carton:

- 2 alcohol pads
- 2 cotton balls or gauze pads
- Special disposal container

Place these items on a clean, flat surface.

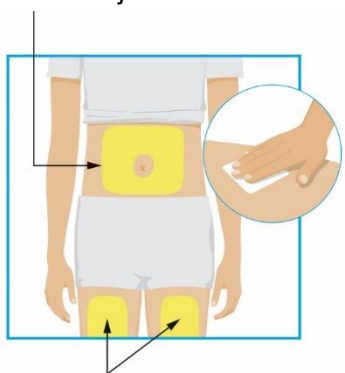
Wash and dry your hands.

Start with one syringe for the first injection.

**For a full dose, 2 injections are required, one after the other.**

##### STEP 2

Areas to inject



Areas to inject

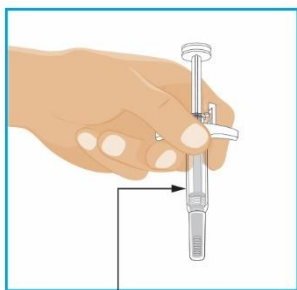
Choose from these 3 areas to inject:

- front of left thigh or right thigh
- belly (abdomen) at least 5 cm (2 inches) from the belly button (navel)

For the second syringe, inject at least 3 cm (1 inch) away from the first injection. **Do not** inject into the same place.

Before each injection, wipe where you will inject in a circular motion with an alcohol pad.

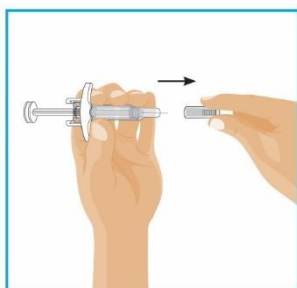
- **Do not** touch or blow on the injection site after it is cleaned. Allow the skin to dry before injecting.
- **Do not** inject through clothes.
- **Do not** inject into skin that is sore, bruised, red, hard, scarred, or has stretch marks.
- **Do not** inject into areas affected by psoriasis.

**STEP 3**

Check liquid

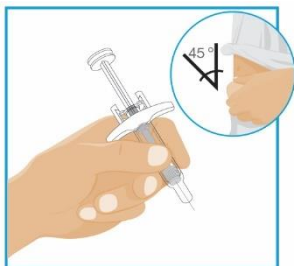
Hold the syringe with covered needle pointing down, as shown. Check the liquid in the syringe.

- It is normal to see bubbles in the window.
- The liquid should look clear to slightly yellow and may contain tiny white or clear particles.
- **Do not** use if the liquid is cloudy or contains flakes or large particles.

**STEP 4**

Removing the needle cover:

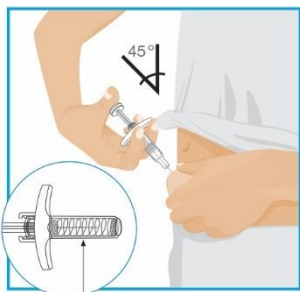
- Hold the syringe in one hand between the finger grip and needle cover.
- With the other hand, gently pull the needle cover straight off.
- **Do not** hold or pull plunger rod when removing the needle cover.
- You may see a drop of liquid at the end of the needle. This is normal.
- Throw away the needle cover.
- **Do not** touch the needle with your fingers or let the needle touch anything.

**Inject Skyrizi****STEP 5**

Hold the body of the syringe in one hand between the thumb and index finger, like you would a pencil.

Gently pinch the area of cleaned skin with your other hand and hold it firmly.

Insert the needle all the way into the skin at about a 45-degree angle using a quick, short movement. Keep the syringe steady at the same angle.

**STEP 6**

Needle guard

Slowly push the plunger rod all the way in until all of the liquid is injected.

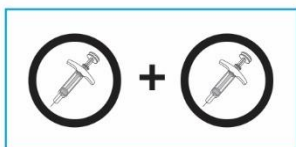
Pull the needle out of the skin while keeping the syringe at the same angle.

Slowly take your thumb off the plunger rod. The needle will then be covered by the needle guard.

- The needle guard will not activate unless all the liquid is injected.
- Speak to your doctor, pharmacist or nurse if you think you have not given a full dose.

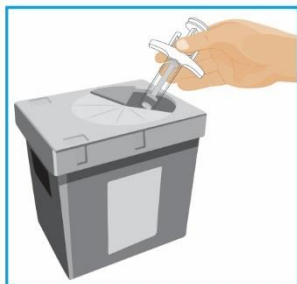
Press a cotton ball or gauze pad where you have injected and hold for 10 seconds.

**Do not** rub the skin where you have injected. You may have slight bleeding from where you injected. This is normal.

**STEP 7**

**For a full dose, two injections are needed, one after the other.**

- Repeat Steps 2 through 6 with the second syringe.
- Inject the second syringe immediately after the first injection, at least 3 cm away from the first injection.

**After your Injection****STEP 8**

Throw away used syringes in a special disposal container right away after use.

- **Do not** throw away used syringes in the household waste.
- Your doctor, pharmacist or nurse will tell you how to return the full special disposal container.

**Need Help?**

Call your doctor to talk about any questions you may have. For questions or concerns visit the manufacturer's website ([www.abbvie.ca](http://www.abbvie.ca)) or call 1-888-704-8271.

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