

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ACTONEL[®]**

risedronate sodium tablets, USP

Read this carefully before you start taking **ACTONEL** 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 **ACTONEL**.

What is **ACTONEL used for?**

ACTONEL is used in adults to:

- treat or prevent osteoporosis in postmenopausal women.
- increase bone density in men with osteoporosis.

How does **ACTONEL work?**

ACTONEL contains the medicinal ingredient risedronate sodium. Risedronate sodium belongs to a class of non-hormonal drugs called bisphosphonates. Bisphosphonates are similar to a molecule naturally made in your body that breaks down bone tissue. **ACTONEL** binds to the receptors in your body to prevent the bone from breaking down. This slows down bone loss which can help to reduce the risk of fractures. In many people **ACTONEL** helps to increase bone density.

What are the ingredients in **ACTONEL?**

Medicinal ingredients: risedronate sodium hemi-pentahydrate

Non-medicinal ingredients: colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, hypromellose, indigo carmine (150 mg), iron oxide (35 mg), lactose monohydrate (35 mg), magnesium stearate, microcrystalline cellulose, polyethylene glycol, and titanium dioxide

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

Film-coated tablets: 35 mg (orange) or 150 mg (blue)

Do not use ACTONEL if:

- you have low levels of calcium in your blood (hypocalcemia).
- you are allergic to risedronate sodium or any of the other ingredients in ACTONEL (see **What are the ingredients in ACTONEL?**).

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

- have or have had problems swallowing or have problems with your esophagus (the tube that connects your mouth to your stomach)
- have or have had stomach or digestive problems
- have or have had kidney problems
- cannot stand or sit upright for at least 30 minutes (see **How to take ACTONEL**)
- are pregnant or breastfeeding
- have one of the following risk factors for developing osteonecrosis (bone damage in the jaw):
 - have cancer and/or are currently receiving chemotherapy
 - are currently having or have had radiotherapy of the head or neck
 - have an infection or a lowered immune system (immunosuppression)
 - are taking corticosteroids (used to treat inflammation) or cancer drugs such as angiogenesis inhibitors (used to slow down the growth of new blood vessels)
 - have diabetes (high blood sugar)
 - have poor oral hygiene or dentures that do not fit well
 - have or have had pain, swelling or numbness of the jaw or loosening of a tooth
 - have sores in your mouth. Your healthcare professional may tell you not to take ACTONEL until all the sores in your mouth have healed.
 - are or have been a smoker
 - have or have had poor dental health, teeth or gum disease
 - have anemia (low red blood cell count)
 - have a blood disorder where your blood cannot form clots in the normal way
- are lactose intolerant or have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in the 35 mg ACTONEL tablets.

Other warnings you should know about:

Gastrointestinal Problems: Taking ACTONEL incorrectly may cause you to experience problems with your esophagus. Stop taking ACTONEL and talk to your healthcare professional if you experience difficulty or pain upon swallowing, chest/breastbone pain or new or worsening heartburn. To avoid problems with your esophagus and to allow the drug to reach the stomach, consider the following instructions:

- swallow each tablet of ACTONEL with a full glass of water.
- do NOT chew or suck the tablet.
- do NOT lie down for at least 30 minutes after taking ACTONEL or until you have had your first meal of the day.
- do NOT take ACTONEL at bedtime or before starting your day.

Eye Problems: Drugs like ACTONEL may cause vision problems. Different parts of your eye may experience inflammation or you may develop an eye infection. Your healthcare professional may end your treatment if they see symptoms of inflammation.

Oral Health: Your healthcare professional should check your mouth and may ask you to see your dentist before you start taking ACTONEL. Dental work should be done before you start treatment with ACTONEL. Tell your healthcare professional if you recently had any major dental procedures like an extraction or a root canal. Take good care of your teeth and gums and see the dentist for regular checkups while taking ACTONEL.

Calcium and Vitamin D: Calcium and vitamin D are also important for strong bones. Your healthcare professional may ask you to take calcium and vitamin D while you are on ACTONEL.

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

The following may interact with ACTONEL:

- Vitamins, mineral supplements and antacids may contain substances that can stop your body from absorbing ACTONEL. They include calcium, magnesium, aluminum and iron. Take these medicines at a different time of day than ACTONEL. Talk to your healthcare professional about how and when to take these medications.
- Taking ACTONEL with corticosteroids or cancer drugs like angiogenesis inhibitors may increase your chance of jaw bone problems (osteonecrosis of the jaw).
- Talk to your healthcare professional before taking pain medication like ASA or other non-steroidal anti-inflammatory drugs (NSAIDs) because they may upset your stomach.

How to take ACTONEL:

- Take ACTONEL exactly as your healthcare professional tells you to.

- Take ACTONEL in the morning **on an empty stomach**, at least 30 minutes before you eat, drink or take other medicines.
- Swallow each ACTONEL tablet whole, while you are sitting or standing in an upright position. Drink enough **plain water** (at least 120 mL or ½ cup) to make sure the tablet gets to your stomach. Do not chew, cut or crush the tablets.
- Do not lie down for at least 30 minutes after taking ACTONEL.

Usual dose:

To treat osteoporosis in women after menopause:

- 35 mg per week of ACTONEL or
- 150 mg per month of ACTONEL

To prevent osteoporosis in women after menopause:

- 35 mg per week of ACTONEL

To increase bone density in men with osteoporosis:

- 35 mg per week of ACTONEL

Overdose:

If you take too much ACTONEL, drink a full glass of milk and tell your healthcare professional immediately. Do not make yourself vomit. Do not lie down.

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

Missed Dose:

Weekly dose (35 mg):

If you missed your dose on your usual day, take one tablet in the morning after you remember. You can go back to your regular schedule for the next dose. If you have missed your dose by one week, do not take 2 tablets on the same day. Skip your missed dose and go back to your regular schedule.

Monthly dose (150 mg):

If you forget to take your monthly dose of ACTONEL, take it next in the morning if your next dose is more than 7 days away. Take your next dose on the regularly scheduled day.

If your next dose is less than 7 days away, wait until your next scheduled dose. Do not take more than 150 mg of ACTONEL within 7 days.

What are possible side effects from using ACTONEL?

These are not all the possible side effects you may have when taking ACTONEL. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- abdominal pain, heartburn, nausea
- diarrhea
- constipation
- flatulence (gas)
- headache
- lack of energy

When you take ACTONEL once a month, it may cause short-lasting, mild flu-like symptoms. These symptoms usually decrease as you keep taking doses.

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	
COMMON			
Pain in bones, joints or muscles	✓		
Esophagus and stomach problems: abdominal pain, pain or trouble swallowing, vomiting blood, heartburn, chest or breastbone pain, black or bloody stool			✓
UNCOMMON			
Eye problems: eye pain, redness or swelling, sensitivity to light, decreased vision			✓
RARE			
Pain in your tongue		✓	
Jaw bone problems (osteonecrosis): numbness or a feeling of heaviness in the jaw; poor healing of gums; loose teeth; exposed bone in the mouth; sores in the mouth; discharge; dry mouth; swelling gums; infections; bad breath; pain in the mouth, teeth or jaw		✓	

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	
VERY RARE			
Allergic reactions: hives, rash (with or without blisters); swelling of the face, lips, tongue or throat; difficult or painful swallowing; trouble breathing			✓
Hypocalcemia (low levels of calcium in the blood): numbness, tingling or muscle spasms		✓	
Atypical femur fractures: new or unusual pain in the hip, groin or thigh		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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 (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 ACTONEL in the original package and store at room temperature (20-25°C).

Keep out of reach and sight of children.

If you want more information about ACTONEL:

- 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:

(www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

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Last Revised NOV 3, 2022

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PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrACTONEL DR[®]

risedronate sodium delayed-release tablets

Read this carefully before you start taking **ACTONEL DR** 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 **ACTONEL DR**.

What is ACTONEL DR used for?

- ACTONEL DR is used to treat osteoporosis in postmenopausal women.

How does ACTONEL DR work?

ACTONEL DR contains the medicinal ingredient risedronate sodium. Risedronate sodium belongs to a class of non-hormonal drugs called bisphosphonates. Bisphosphonates are similar to a molecule naturally made in your body that breaks down bone tissue. ACTONEL DR binds to the receptors in your body to prevent the bone from breaking down. This slows down bone loss which can help to reduce the risk of fractures. In many people ACTONEL DR helps to increase bone density.

What are the ingredients in ACTONEL DR?

Medicinal ingredients: risedronate sodium hemi-pentahydrate

Non-medicinal ingredients: edetate disodium, iron oxide yellow, magnesium stearate, methacrylic acid copolymer dispersion, polysorbate 80, silicified microcrystalline cellulose, simethicone, sodium starch glycolate, stearic acid, talc and triethyl citrate

ACTONEL DR comes in the following dosage form:

Enteric-coated tablets: 35 mg (yellow).

The ACTONEL DR tablet has an enteric coating which delays the release of risedronate until it reaches the small intestine.

Do not use ACTONEL DR if:

- you have low levels of calcium in your blood (hypocalcemia)
- you are allergic to risedronate sodium or any of the other ingredients in ACTONEL DR (see **What are the ingredients in ACTONEL DR?**)

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

- have or have had problems swallowing or have/had problems with your esophagus (the tube that connects your mouth to your stomach)
- have or have had stomach or digestive problems
- have or have had kidney problems
- cannot stand or sit upright for at least 30 minutes (see **How to take ACTONEL DR**)
- are pregnant or breastfeeding
- have one of the following risk factors for developing osteonecrosis (bone damage in the jaw):
 - have cancer and/or are currently receiving chemotherapy
 - are currently having or have had radiotherapy of the head or neck
 - have an infection or a lowered immune system (immunosuppression)
 - are taking corticosteroids (used to treat inflammation) or cancer drugs such as angiogenesis inhibitors (used to slow down the growth of new blood vessels)
 - have diabetes (high blood sugar)
 - have poor oral hygiene or dentures that do not fit well
 - have or have had pain, swelling or numbness of the jaw or loosening of a tooth
 - have sores in your mouth. Your healthcare professional may tell you not to take ACTONEL DR until all the sores in your mouth have healed.
 - are or have been a smoker
 - have or have had poor dental health, teeth or gum disease
 - have anemia (low red blood cell count)
 - have a blood disorder where your blood cannot form clots in the normal way

Other warnings you should know about:

Gastrointestinal Problems: Taking ACTONEL DR incorrectly may cause you to experience problems with your esophagus. Stop taking ACTONEL DR and talk to your healthcare professional if you experience difficulty or pain upon swallowing, chest/breastbone pain or new or worsening heartburn. To avoid problems with your esophagus and to allow the drug to reach the stomach, consider the following instructions:

- swallow each tablet of ACTONEL DR with a full glass of water.

- do NOT chew or suck the tablet.
- do NOT lie down for at least 30 minutes after taking ACTONEL DR.
- do NOT take ACTONEL DR at bedtime or before starting your day.

Eye Problems: Drugs like ACTONEL DR may cause vision problems. Different parts of your eye may experience inflammation or you may develop an eye infection. Your healthcare professional may end your treatment if they see symptoms of inflammation.

Oral Health: Your healthcare professional should check your mouth and may ask you to see your dentist before you start taking ACTONEL DR. Dental work should be done before you start treatment with ACTONEL DR. Tell your healthcare professional if you recently had any major dental procedures like an extraction or a root canal. Take good care of your teeth and gums and see the dentist for regular checkups while taking ACTONEL DR.

Calcium and Vitamin D: Calcium and vitamin D are also important for strong bones. Your healthcare professional may ask you to take calcium and vitamin D while you are on ACTONEL DR.

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

The following may interact with ACTONEL DR:

- Vitamins, mineral supplements and antacids may contain substances that can stop your body from absorbing ACTONEL DR. They include calcium, magnesium, aluminum and iron. Take these medicines at a different time of day than ACTONEL DR. Talk to your healthcare professional about how and when to take these medications.
- Taking ACTONEL DR with corticosteroids or cancer drugs like angiogenesis inhibitors may increase your chance of jaw bone problems (osteonecrosis of the jaw).
- Talk to your healthcare professional before taking pain medication like ASA or other non-steroidal anti-inflammatory drugs (NSAIDs) because they may upset your stomach.

How to take ACTONEL DR:

- Take ACTONEL DR exactly as your healthcare professional tells you to.
- On the same day each week, take ACTONEL DR in the morning with breakfast (including high fat foods, coffee, tea, milk, orange juice etc.). Do not take ACTONEL DR before food or on an empty stomach as it may cause abdominal pain.

- Swallow each ACTONEL DR tablet whole, while you are sitting or standing in an upright position. Do not chew, cut or crush the tablets or break the outer coating. Drink enough plain water (at least 120 mL or ½ cup) to make sure the tablet gets to your stomach.
- Do not lie down for at least 30 minutes after taking ACTONEL DR.

Usual dose:

- 1 ACTONEL DR 35 mg tablet per week

Overdose:

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

Missed Dose:

If you forget to take ACTONEL DR on your usual day take it in the morning after you remember. You can go back to your regular schedule for the next dose. If you have missed your dose by 1 week do not take two tablets on the same day. Skip your missed dose and go back to your regular schedule.

What are possible side effects from using ACTONEL DR?

These are not all the possible side effects you may have when taking ACTONEL DR. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- abdominal pain, heartburn, nausea, vomiting
- diarrhea, constipation
- stuffy nose, sore throat

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	
COMMON			
Pain in bones, joints or muscles	✓		
Esophagus and stomach problems: abdominal pain, pain or trouble swallowing, vomiting blood, heartburn,			✓

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	
chest/breastbone pain, black or bloody stool UNCOMMON			
Eye problems: eye pain, redness or swelling, sensitivity to light, decreased vision RARE			✓
Pain in your tongue		✓	
Jaw bone problems (osteonecrosis): numbness or a feeling of heaviness in the jaw; poor healing of gums; loose teeth; exposed bone in the mouth; sores in the mouth; discharge; dry mouth; swelling gums; infections; bad breath; pain in the mouth, teeth or jaw VERY RARE		✓	
Allergic reactions: hives, rash (with or without blisters); swelling of the face, lips, tongue or throat; difficult or painful swallowing; trouble breathing			✓
Hypocalcemia (low levels of calcium in the blood): numbness, tingling or muscle spasms		✓	
Atypical femur fracture: new or unusual pain in the hip, groin or thigh		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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 (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 ACTONEL DR in the original package and store at room temperature (20-25°C).

Keep out of reach and sight of children.

If you want more information about ACTONEL DR:

- 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: (www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation

Last Revised NOV 3, 2022

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