

## **PATIENT MEDICATION INFORMATION**

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

Pr **SALOFALK**<sup>®</sup>

#### **Mesalamine delayed release tablets**

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

#### **What is SALOFALK used for?**

SALOFALK is used to:

- treat inflammation of the lining of the large bowel and rectum (acute ulcerative colitis).
- prevent the return of Crohn's disease in patients who have had bowel resection, a surgery to remove part of the intestines.

#### **How does SALOFALK work?**

SALOFALK is believed to reduce the activity of certain chemicals in your body that cause inflammation (e.g., prostaglandins). This helps to reduce the swelling and pain in your rectum and lower part of your large bowel.

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

Medicinal ingredients: mesalamine (me-SAL-a-meen), also known as 5-aminosalicylic acid, 5-ASA or mesalazine.

Non-medicinal ingredients: carnauba wax, colloidal silicon dioxide, glycine, hydroxypropyl methylcellulose, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, polydimethyl siloxane, polysorbate, povidone, sodium carbonate, sodium hydroxide, talc, titanium dioxide, triethyl citrate.

SALOFALK is gluten-free and phthalate-free.

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

Delayed release tablets, 500 mg.

#### **Do not use SALOFALK if:**

- you have severe kidney problems
- you have severe liver problems
- you are allergic to mesalamine or to any of the non-medicinal ingredients in SALOFALK, or component of the container (see **What are the ingredients in SALOFALK?**)

- you have stomach or small intestinal ulcers
- you have a blockage in your urinary tract
- you have a sensitivity to a family of drugs known as salicylates, which includes acetylsalicylic acid (ASA)
- you are unable to swallow the tablet whole

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

- have any kidney or liver problems
- have heart problems, including a history of heart inflammation (which may be the result of an infection of the heart)
- have stomach pain
- have had an unusual or allergic reaction to sulfasalazine (SAS), an ingredient in medicines used to treat ulcerative colitis
- have bleeding or clotting problems
- have pyloric stenosis (a narrowing of the outlet from the stomach that causes contents of the stomach to remain there for a longer period of time)

**Other warnings you should know about:**

**Serious Side Effects:** SALOFALK can cause serious side effects:

- **Serious skin reactions:** Severe cutaneous adverse reactions (SCAR), including Stevens-Johnson syndrome (SJS), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and toxic epidermal necrolysis (TEN) have happened in people taking SALOFALK. These skin reactions are serious. Stop taking SALOFALK and get immediate medical help if you experience any signs of a severe skin reaction, such as mouth sores, a severe skin rash, or any other signs of an allergic reaction.
- **Kidney problems, including kidney stones:** People taking SALOFALK can develop kidney stones or other kidney problems. Symptoms may include blood in your urine, urinating more often and pain in your back, side, belly or groin. Be sure to drink enough liquids while you are taking SALOFALK. Talk to your healthcare professional about how much water or other liquids you should be drinking.
- **Acute Intolerance Syndrome:** Symptoms of acute intolerance syndrome can be similar to a flare of your condition. If you think you are experiencing a flare, talk to your healthcare professional immediately.
- **Heart problems:** These include inflammation of the heart muscle (myocarditis) and inflammation of the tissue around the heart (pericarditis).
- **Blood problems:** This includes low numbers of all types of blood cells (myelosuppression).
- **Liver problems:** This included liver failure.

For more information on these and other serious side effects see the **Serious side effects and what to do about them** table, below.

**Pregnancy and Breastfeeding:**

- Talk to your healthcare professional if you are pregnant or thinking of becoming pregnant.
- You should not breastfeed while you are taking SALOFALK. SALOFALK passes into breastmilk.
- If you breastfeed your baby while taking SALOFALK, your baby could develop/start to have diarrhea. It is important to monitor your baby's stool and contact your healthcare professional right away if they have diarrhea. Your healthcare professional may advise you to stop breastfeeding your baby.

**Sensitivity to the sun:** Tell your healthcare professional if you have eczema or atopic dermatitis. Your skin may be more sensitive to sunlight when taking SALOFALK. You should avoid the sun and wear protective clothing and a broad-spectrum sunscreen when you are outdoors.

**Blood tests:** SALOFALK can cause abnormal blood test results. Your healthcare professional will do blood tests before you start taking SALOFALK and periodically during treatment. They will check the health of your liver and kidneys as well as the levels of your red and white blood cells and monitor you for other side effects. Your healthcare professional will decide when to perform blood tests and will interpret the results.

**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 SALOFALK:**

- Other medicines used to treat ulcerative colitis, such as azathioprine, 6-mercaptopurine, aminosalicylates
- sulfonyleureas, used to treat diabetes
- anti-inflammatory drugs (NSAIDS), used to treat pain and inflammation
- anticoagulants, used to thin the blood and prevent blood clots, such as coumarin
- methotrexate, used to treat cancer and severe inflammatory conditions
- medicines used to treat gout, such as probenecid, sulfinpyrazone
- medicines used to treat high blood pressure, such as spironolactone, furosemide
- rifampicin, an antibiotic used to treat bacterial infections
- the chicken pox vaccine (varicella virus vaccine)

**How to take SALOFALK:**

- Take SALOFALK exactly as your healthcare professional has told you. Your healthcare professional will decide on the dose that is right for you. Do not stop taking SALOFALK without talking to your healthcare professional.
- Tablets should be swallowed whole before meals with liquid. Do not crush the tablets.

**Usual dose:**

For the treatment of acute ulcerative colitis: Two 500 mg SALOFALK tablets, three or four times daily.

For the prevention of the return of Crohn's disease in patients after bowel resection: 3000 mg per day in divided doses.

**Overdose:**

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

**Missed Dose:**

If you miss a dose of SALOFALK, take your dose as soon as possible, unless it is almost time for the next dose. Do not take two doses at the same time to make up for a missed dose.

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

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

Side effects may include:

- anorectal pain or discomfort
- stomach pain or discomfort
- nausea
- bloating, gas
- constipation
- diarrhea
- discoloured stool
- dizziness
- fever
- flu-like symptoms
- hemorrhoids
- hair loss
- headache
- inflammation/swelling of the throat or tongue
- tongue discoloration
- burning or tingling sensation in the mouth
- itching, rash, skin redness
- joint, back or neck pain
- sleeplessness
- swollen hands or lower legs

- tiredness or weakness
- abnormal urine color
- cough
- decrease in sperm count

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>			
<b>Kidney stones</b> (hard little pebbles that form in your kidneys): blood in urine, urinating more often, pain in your back, side, belly or groin		✓	
<b>Urinary tract infection:</b> strong, persistent urge to urinate, pain or burning when urinating, bloody, cloudy or strong smelling urine, passing frequent, small amounts of urine		✓	
<b>UNKNOWN</b>			
<b>Pancreatitis</b> (inflammation of the pancreas): abdominal pain, nausea, vomiting, fever, rapid heartbeat, feeling tired			✓
<b>Allergic reaction:</b> rash, hives, itching, fever, swelling of the mouth, lips, tongue or throat, difficulty in swallowing or breathing			✓
<b>Heart problems</b> (including myocarditis, pericarditis or heart inflammation): chest pain, fast or irregular heartbeat, fatigue, fever, difficulty in breathing, accumulation of fluid in the lung, cough			✓
<b>Kidney problems</b> (inflammation of the kidney or kidney failure): blood in the urine, fever, increased or decreased urine output, mental status changes (drowsiness, confusion, coma), rash, swelling of the body, weight gain (from retaining fluid)			✓
<b>Liver problems</b> (including liver failure): severe abdominal pain, nausea, vomiting, yellowing of the skin and eyes, loss of appetite, bloating and distension, Dark urine, pale stool			✓
<b>Acute intolerance syndrome:</b> cramping, stomach pain, bloody and excessive stools, fever, headache, rash			✓
<b>Lung problems:</b> difficulty in breathing, dry cough, fever, chills, sweating, body aches, generally feeling unwell			✓

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>Blood problems</b> (low levels of one or more types of blood cells): fatigue, difficulty in breathing with exertion, rapid or irregular heartbeat, pale skin, frequent or prolonged infections, unexplained or easy bruising, nosebleeds, bleeding gums, prolonged bleeding from cuts, skin rash, dizziness, headache			✓
<b>Serious skin reactions</b> (SCAR, DRESS, SYS, TEN): reddish, flat circular patches with blisters on the skin or inside the mouth, eyes, nose, or genitals, fever, severe skin rash, peeling skin, swollen lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often			✓
<b>Pleurisy</b> (accumulation of fluid in the lungs): dry cough, chest pain, difficulty breathing			✓
<b>Increased pressure in brain:</b> headache which may originate behind your eyes and worsen with eye movements, with blurred or dimmed vision, double vision, seeing light flashes, difficulty seeing to the side, and brief or permanent vision loss, dizziness, nausea, vomiting, ringing in ears			✓
<b>Worsening of ulcerative colitis:</b> worsening of stomach cramps or pain or diarrhea		✓	
<b>Photosensitivity</b> (sensitivity of the skin to the sun): rash, redness, blisters, itching and burning when the skin is exposed to the sun or UV light	✓		

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 (<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:**

SALOFALK should be stored at room temperature (15-30°C). Protect from exposure to light and moisture.

Keep out of reach and sight of children.

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

- 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.

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