

## **PATIENT MEDICATION INFORMATION**

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

Pr **SALOFALK**<sup>®</sup>

#### **Mesalamine rectal suspension USP**

Read this carefully before you start using **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 4 g/60 g is used to manage a condition called distal ulcerative colitis (inflammation of the lining of the large bowel and rectum). It may also be used to prevent the symptoms of the disease from happening again. SALOFALK 4 g/60 g can be used in combination with other drugs.

SALOFALK 2 g/60 g is used to prevent the symptoms of distal ulcerative colitis from happening again.

#### **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: carbomer, edetate disodium, potassium acetate, potassium metabisulfite, purified water, sodium benzoate and xanthan gum.

SALOFALK is gluten-free and phthalate-free.

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

Rectal suspension: 2 g/60 g and 4 g/60 g

#### **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 a sensitivity to a family of drugs known as salicylates, which includes acetylsalicylic acid (ASA)
- you have stomach or small intestinal ulcers
- you have a blockage in your urinary tract
- the patient is an infant under two years of age

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you use 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, or sulphites
- have bleeding or clotting problems

**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 the urine, urinating more often and pain in your back, side, belly or groin. Be sure to drink enough liquids while you are using 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. They will also check to see how well you are responding to SALOFALK. 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, aminosaliculates
- sulfonylureas, 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 use SALOFALK:**

- Take SALOFALK exactly as your healthcare professional has told you. Your healthcare professional will tell you which strength of SALOFALK to use and how often you should use it. They may adjust your dose as needed. Do not stop using SALOFALK without talking to your healthcare professional.
  - You will achieve the best results if you empty your bowel immediately before using SALOFALK.
1. Preparing the medication for administration:
    - a) Shake the bottle well to make sure that the suspension is all one colour.
    - b) Remove the protective sheath from the applicator tip. Hold the bottle at the neck so that the medication does not fall out of the bottle.

2. Getting into the correct body position:
  - a) Lay on your left side with your left leg extended. Bend your right leg forward for balance. You can also lay the other way around if you are left-handed.
  - b) Instead of lying down on your side, you can also be in the “knee-chest” position.
3. Administering the rectal suspension:
  - a) Gently insert the lubricated applicator tip into your rectum, pointed slightly toward the navel (belly-button).
  - b) Hold the bottle firmly, then tilt it slightly so that the nozzle is aimed toward your back. Squeeze slowly to release the medication. Keep your hand at a steady pressure. This will discharge most of the suspension. After administering, withdraw and discard the used bottle.
  - c) Remain in this position for at least 30 minutes for maximum benefit. Keep the suspension in your rectum all night, if possible.

**Usual dose:**

**When you are experiencing symptoms (acute episodes):**

Use one 4 g/60 g bottle daily at bedtime.

**To prevent symptoms from reoccurring (prevention of relapses):**

Use one 2 g/60 g bottle daily at bedtime. Depending on your condition, your healthcare professional may tell you to use one bottle every second or third day.

**Overdose:**

If you think you, or a person you are caring for, have used 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, use it as soon as possible, unless it is almost time for the next dose. Do not use two SALOFALK 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 using SALOFALK. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- anorectal pain, discomfort or discharge
- stomach pain, cramps or discomfort

- nausea
- bloating, gas
- constipation
- diarrhea
- incomplete bowel movements
- discoloured stool
- dizziness
- fever
- flu-like symptoms
- hemorrhoids
- hair loss
- headache
- inflammation/swelling of the throat
- itching, rash
- lower back, joint or neck pain
- reaction at site of administration
- sleeplessness
- swollen hands or lower legs
- tiredness or weakness
- abnormal urine colour
- cough
- medication residue

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop using 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		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop using drug and get immediate medical help
	Only if severe	In all cases	
<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>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), swelling of the body, weight gain (from retaining fluid)			✓
<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>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			✓
<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>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			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop using drug and get immediate medical help
	Only if severe	In all cases	
permanent vision loss, dizziness, nausea, vomiting, ringing in ears			
<b>Serious skin reactions</b> (SCAR, DRESS, SJS, 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>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:

Store SALOFALK at room temperature, preferably under 25°C. The expiration date and lot number are printed on the bottle.

Suspension colour may vary from off white to brown. Keep the medicine from light and air.

Keep out of reach and sight of children.

NOTE: SALOFALK will cause staining of direct contact surfaces, including but not limited to fabrics, flooring, painted surfaces, marble, granite, vinyl, and enamel.

**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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