

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **SALOFALK**[®]

Mesalamine suppositories

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 is used:

- to manage a condition called ulcerative proctitis, in which the rectum is inflamed.
- as a combination therapy for severe inflammation of the lining of the large bowel and rectum (distal ulcerative colitis).

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: Witepsol H-15 (suppository wax base).

SALOFALK is gluten-free and phthalate-free.

SALOFALK comes in the following dosage forms:

Suppositories: 500 mg or 1000 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 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
- 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. 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, sulfipyrazone
- 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 how many SALOFALK suppositories to use. They may adjust your dose as needed. Do not stop using SALOFALK without talking to your healthcare professional.
- Detach one suppository from the strip of suppositories.
- Hold the suppository upright and carefully remove the plastic wrapper.
- Avoid touching the suppository for too long. This is because the suppository can melt at body temperature.
- Insert the pointed end of the suppository completely into your rectum. Insert it with gentle pressure.
- You may use a small amount of lubricating gel on the tip of the suppository to help with the insertion. Keep the suppository in your rectum for one to three hours or longer, if possible.

Usual dose:

500 mg SALOFALK: one suppository, two or three times daily.

1000 mg SALOFALK: one suppository, once daily, at bedtime.

The usual adult dose is 1000 mg - 1500 mg per 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 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
- anal itching
- stomach pain, cramps or discomfort
- nausea, vomiting
- bloating, gas
- constipation
- diarrhea
- painful or incomplete bowel movements
- abnormal stool (frequent bowel movements, stools discoloured, mucous in stool)
- dizziness
- fever
- flu like symptoms
- hemorrhoids
- hair loss
- headache
- inflammation/swelling of the throat
- itching, rash, skin redness
- joint and lower back pain
- reaction at site of administration
- sleeplessness

- swollen hands or lower legs
- tiredness or weakness
- cough
- difficulty breathing
- eye swelling
- medication residue
- pain

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	
UNCOMMON			
Kidney stones (hard little pebbles that form in your kidneys): blood in urine, urinating more often, pain in your back, side, belly or groin		✓	
Urinary tract infection: strong, persistent urge to urinate, pain or burning when urinating, bloody, cloudy or strong smelling urine, passing frequent, small amounts of urine		✓	
UNKNOWN			
Pancreatitis (inflammation of the pancreas): abdominal pain, nausea, vomiting, fever, rapid heartbeat, feeling tired			✓
Allergic reaction: rash, hives, itching, fever, swelling of the mouth, lips, tongue or throat, difficulty in swallowing or breathing			✓
Heart problems (including myocarditis, pericarditis or heart inflammation): chest pain, fast or irregular heartbeat, fatigue, fever, difficulty in breathing, accumulation of fluid in the lung, cough			✓
Kidney problems (inflammation of the kidney or kidney failure): blood in the urine, fever, increased or decreased urine output, mental status changes (drowsiness, confusion, coma), rash,			✓

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	
swelling of the body, weight gain (from retaining fluid)			
Liver problems (including liver failure): severe abdominal pain, nausea, vomiting, yellowing of the skin and eyes, loss of appetite, bloating and distension, dark urine, pale stool			✓
Acute intolerance syndrome: cramping, stomach pain, bloody and excessive stools, fever, headache, rash			✓
Lung problems: difficulty in breathing, dry cough, fever, chills, sweating, body aches, generally feeling unwell			✓
Blood problems (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			✓
Serious skin reactions (SCAR, DRESS, SJS, TEN): reddish, flat circular patches with blisters on the skin or inside the mouth, eyes, nose, or genitals, fever, severe 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			✓
Pleurisy (accumulation of fluid in the lungs): dry cough, chest pain, difficulty in breathing			✓
Increased pressure in brain: 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			✓

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	
Worsening of ulcerative colitis: worsening of stomach cramps or pain or diarrhea		✓	
Photosensitivity (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 must be stored below 25°C. Can be refrigerated. Keep away from direct heat, light and humidity.

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, or by calling 1-888-704-8271.

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