

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **SALOFALK**[®]

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 in preventing the symptoms of the disease from happening again. SALOFALK 4 g/60 g can be used in combination with other drugs.

The lower strength of SALOFALK 2 g/60 g may also be used in preventing 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 are a patient with severe kidney (renal) problems and/or severe liver (hepatic) problems
- You are allergic to mesalamine or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container
- You have a sensitivity to salicylates, for example acetylsalicylic acid (Aspirin[®])

- 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 eczema (dry, itchy rashes on your skin) or a skin condition called atopic dermatitis.
- have a pre-existing liver disease. There have been reports of liver (hepatic) failure and increased liver enzymes in patients treated with 5-ASA or mesalazine (=mesalamine) products.
- have inflammation of the heart muscle and lining around the heart. Your healthcare professional will decide if this product is right for you.
- have stomach pain
- have mild to moderate problems with your liver function. Your healthcare professional will decide if this product is right for you.
- ever had any unusual or allergic reaction to sulfasalazine (SAS) or sulphites
- have mild to moderate problems with your kidney. Your healthcare professional will decide if this product is right for you.
- have bleeding or clotting disorders
- have higher than normal blood urea nitrogen (BUN) levels (kidney function test)
- have higher than normal serum creatinine levels (kidney function test)
- have higher than normal proteins in your urine (proteinuria)
- are pregnant or breastfeeding. Mesalamine is excreted in human breast milk. Your healthcare professional will decide if this product is right for you.

While using SALOFALK:

- Discontinue use at first sign of rash or fever.
- Your healthcare professional may test your blood or urine regularly to monitor your kidney function since prolonged use of SALOFALK may damage your kidneys.

Other warnings you should know about:

Kidney stones may develop with use of mesalamine. Symptoms may include blood in 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.

If you breastfeed your baby while taking SALOFALK, your baby could develop/start to have diarrhoea. It is important to monitor your baby's stool and contact your healthcare professional right away if they have diarrhoea. Your healthcare professional may advise you to stop breastfeeding your baby.

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.

SALOFALK can cause serious skin reactions. Stop taking SALOFALK and get immediate medical help if you have any symptoms of serious skin reactions. These include: reddish, flat circular patches with blisters on the skin or inside the mouth, eyes, nose, or genitals. Fever may occur before the severe skin rashes appear.

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:

Interaction between azathioprine, 6-mercaptopurine, sulfonyleureas, anti-inflammatory drugs (NSAIDs) and aminosalicylates (such as SALOFALK) has been reported.

Drug interactions with coumarin, methotrexate, probenecid, sulfinpyrazone, spironolactone, furosemide, rifampicin, and Varicella Virus Vaccine (chicken pox vaccine) may be possible.

How to use SALOFALK:

- Take SALOFALK exactly as your healthcare professional has told you.

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 lubricated applicator tip into your rectum, pointed slightly toward the navel (umbilicus).
- b) Hold the bottle firmly, then tilt slightly so that the nozzle is aimed toward the back, and 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. Keep the medication in your rectum for as long as possible. This will help to achieve the maximum benefit.

Your healthcare professional may run tests to see how you are responding to the medication. Your healthcare professional may adjust your dose as needed. Do not stop taking SALOFALK without discussing it with your healthcare professional first.

To prevent symptoms from reoccurring (prevention of relapses):

Use one 2 g/60 g bottle daily at bedtime to prevent your symptoms from coming back. Alternatively, use 4 g/60 g bottle every second or third day, depending upon your condition.

Continued use for a certain period may be recommended by your healthcare professional to prevent symptoms from recurring. Check with your healthcare professional should symptoms such as diarrhoea and rectal bleeding recur.

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 feel when using SALOFALK. If you experience any side effects not listed here, tell your healthcare professional.

Side-effects reported during clinical trials with SALOFALK include:

- anorectal pain or discomfort
- bloating
- constipation
- diarrhoea
- dizziness

- fever
- flu like symptoms
- haemorrhoids
- hair loss
- having gas (flatulence)
- headache
- inflammation/swelling of the throat
- itching
- lower back or joint pain
- nausea
- rash
- reaction at site of administration
- sleeplessness
- stomach pain
- swollen hands or lower legs
- tiredness or weakness
- urinary tract infection

Side effects reported with post-marketing use of SALOFALK:

- abnormal stool colour
- abnormal urine colour
- cough
- feeling of incomplete defecation
- hives
- increased sensitivity to sunlight
- medication residue
- neck pain
- stomach cramps or discomfort

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			
Chest 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	
Kidney stones (hard little pebbles that form in your kidneys): blood in urine, urinating more often and pain in your back, side, belly or groin.		✓	
UNKNOWN			
Pancreatitis (inflammation of the pancreas): abdominal pain, nausea, vomiting, fever, rapid heartbeat, and feeling tired.			✓
Allergic reaction (hypersensitivity): rash, itching, fever, swelling of the mouth and throat, and difficulty in breathing.			✓
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), swelling of the body, weight gain (from retaining fluid).			✓
Myocarditis/ Pericarditis (inflammation of the heart muscle and lining around the heart): pain in the chest, abnormal heartbeat, fatigue, fever, difficulty in breathing, accumulation of fluid in the lung, and coughing.			✓
Liver problems/Hepatitis (inflammation of the liver): severe abdominal pain, nausea, vomiting, yellowing of the skin and eyes, drop in appetite, bloating and distension.			✓
Acute intolerance syndrome: cramping, stomach pain, bloody and excessive stools, fever, headache and rash.			✓
Interstitial pneumonia (lung abnormality with scarring): difficulty in breathing, dry cough, fever, and persistent unwell feeling.			✓
Blood Problems/Aplastic anaemia/Agranulocytosis (shortage 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, and headache.			✓
Pleurisy (accumulation of fluid in the lungs): dry cough, chest pain, difficulty breathing.			✓

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	
Serious Skin Conditions: reddish, flat circular patches with blisters on the skin or inside the mouth, eyes, nose, or genitals. Fever may occur before the severe skin rashes appear.			✓
Worsening of ulcerative colitis: worsening of stomach cramps or pain or diarrhoea.		✓	

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 or by calling 1-888-704-8271.

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