

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **SALOFALK**[®]

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.

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 are a patient with severe kidney (renal) problems and/or severe liver (hepatic) problems
- You are allergic to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container
- You have stomach or small intestinal ulcers
- You have a blockage in your urinary tract
- You have a sensitivity to salicylates, for example acetylsalicylic acid (Aspirin[®])

- You are unable to swallow the intact tablet

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 eczema (dry, itchy rashes on your skin) or a skin condition called atopic dermatitis.
- have a liver disease. There have been reports of liver 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)
- 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)
- 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). Pyloric stenosis may keep the SALOFALK tablet from reaching the colon as quickly as it normally would.
- are pregnant or breastfeeding. Mesalamine is excreted in human breast milk. Your healthcare professional will decide if this product is right for you.

WHILE taking 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. This is because 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 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.

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 take SALOFALK:

- Take SALOFALK exactly as your healthcare professional has told you.
- 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: 3 g per day in divided doses.

Your healthcare professional will tell you exactly how much SALOFALK to take.

Tablets should be taken consistently for treatment success. Abrupt discontinuation is not recommended.

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 reported with SALOFALK during clinical trials 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, joint or back pain, nausea, rash, sleeplessness, stomach pain, swollen hands or lower legs, tiredness or weakness and urinary tract infection.

Side effects identified with post-marketing use of SALOFALK include: abnormal urine color, burning or tingling sensation in the mouth, cough, decrease in sperm count, hives, increased sensitivity to sunlight, neck pain, redness of the skin, stomach discomfort, stools discoloured, tongue discoloration and tongue swelling.

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	
UNCOMMON			
Chest Pain			✓
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.			✓
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.			✓
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, swelling of the body, weight gain (from retaining fluid).			✓

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	
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/Agranulocytosis/Aplastic anaemia (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.			✓
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.			✓
Pleurisy (accumulation of fluid in the lungs): dry cough, chest pain, difficulty breathing.			✓
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:

SALOFALK should be stored at controlled 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 or by calling 1-888-704-8271.

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