

## **PATIENT MEDICATION INFORMATION**

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

Pr **SALOFALK**<sup>®</sup>

#### **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 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<sup>®</sup>)
- 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 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)
- 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. This is because prolonged use of SALOFALK may damage your kidneys.

**Other warnings you should know about:**

Kidney stones may develop with use of mesalazine. 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 aminosaliclates (such as SALOFALK) has been reported.

Drug interactions with coumarin, methotrexate, probenecid, sulfipyrazone, 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.

Patient Instructions:

- Detach one suppository from the strip of suppositories.
- Hold 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. This will help achieve the maximum benefit.

Your healthcare professional may adjust your dose as needed. Do not stop using the suppositories without discussing it with your healthcare professional first.

**Usual dose:**

One 500 mg SALOFALK suppository, two or three times daily.

One 1000 mg SALOFALK suppository once daily, at bedtime.

The usual adult dose is 1.0 - 1.5 g per day.

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

**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 feel when using 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 and lower back pain
- nausea
- rash
- reaction at site of administration
- sleeplessness
- stomach pain
- swollen hands or lower legs

- tiredness or weakness
- urinary tract infection

Side effects identified with post-marketing use of SALOFALK include:

- abnormal stool (frequent bowel movements, stools discoloured)
- anal itching
- cough
- difficulty breathing
- eye swelling
- feeling of incomplete or painful defecation
- hives
- increased sensitivity to sunlight
- medication residue
- mucus in stools
- pain
- painful bowel movements
- redness of the skin
- rectal pain and discharge
- stomach cramps or discomfort
- vomiting

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>Chest Pain</b>			✓
<b>Kidney stones</b> (hard little pebbles that form in your kidneys): blood in urine, urinating more often and pain in your back, side, belly or groin		✓	
<b>UNKNOWN</b>			
<b>Pancreatitis</b> (inflammation of the pancreas): abdominal pain, nausea, vomiting, fever, rapid heartbeat, and feeling tired			✓

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>Allergic reaction</b> (hypersensitivity): rash, itching, fever, swelling of the mouth and throat, and difficulty in breathing			✓
<b>Myocarditis / Pericarditis</b> (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			✓
<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 / Hepatitis</b> (inflammation of the liver): severe abdominal pain, nausea, vomiting, yellowing of the skin and eyes, drop in appetite, bloating and distension			✓
<b>Acute intolerance syndrome:</b> cramping, stomach pain, bloody and excessive stools, fever, headache and rash			✓
<b>Interstitial pneumonia</b> (lung abnormality with scarring): difficulty in breathing, dry cough, fever, and persistent unwell feeling			✓
<b>Blood problems / Agranulocytosis / Aplastic anaemia</b> (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			✓
<b>Serious skin conditions:</b> reddish, flat circular patches with blisters on the			✓

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	
skin or inside the mouth, eyes, nose, or genitals. Fever may occur before the severe skin rashes appear.			
<b>Pleurisy</b> (accumulation of fluid in the lungs): dry cough, chest pain, difficulty in breathing			✓
<b>Worsening of ulcerative colitis:</b> 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 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](http://www.abbvie.ca), or by calling 1-888-704-8271.

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