

Package leaflet: Information for the user

Salofalk® 1g/Actuation Rectal Foam mesalazine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet

1. What Salofalk rectal foam is and what it is used for
2. What you need to know before you use Salofalk rectal foam
3. How to use Salofalk rectal foam
4. Possible side effects
5. How to store Salofalk rectal foam
6. Contents of the pack and other information

1. What Salofalk rectal foam is and what it is used for

Salofalk rectal foam contains the active substance mesalazine, an anti-inflammatory agent used to treat inflammatory bowel disease.

Salofalk rectal foam is used for the treatment of:

- Inflammation of the large intestine (colon) and rectum (back passage) known by doctors as ulcerative colitis.

2. What you need to know before you use Salofalk rectal foam

Do not use Salofalk rectal foam

- If you are allergic to mesalazine, to salicylic acid, to salicylates such as acetylsalicylic acid (e.g., Aspirin®) or to any of the other ingredients of this medicine (listed in section 6)
- If you have a serious liver or kidney disease.

Warnings and precautions

Before you start using this medicine you should tell your doctor

- If you have a history of problems with your lungs, particularly if you suffer from **bronchial asthma**.
- If you have a history of **allergy to sulphasalazine**, a substance related to mesalazine.
- If you suffer with problems of your **liver**.
- If you suffer with problems of your **kidney**.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Mesalazine may produce red-brown urine discoloration after contact with sodium hypochlorite bleach in the toilet water. It concerns a chemical reaction between mesalazine and bleach and is harmless.

Further precautions:

During treatment your doctor may want to keep you under close medical supervision, and you may need to have regular blood and urine tests.

Kidney stones may develop with use of mesalazine. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with mesalazine.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) have been reported in association with mesalazine treatment. Stop using mesalazine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears contact your doctor immediately.

Other medicines and Salofalk rectal foam

Please tell your doctor if you take or use any of the medicines mentioned below, as the effects of these medicines may change (interactions):

- Certain agents that inhibit blood clotting (**medicines for thrombosis or to thin your blood, e.g. warfarin**).
- **Azathioprine, 6-mercaptopurine or thioguanine** (medicines used to treat immune disorders).

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. It may still be all right for you to use Salofalk rectal foam and your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should only use Salofalk rectal foam during pregnancy if your doctor tells you to.

You should also only use Salofalk rectal foam during breast-feeding if your doctor tells you to, as this medicine may pass into breast milk.

Driving and using machines

There are no effects on the ability to drive and use machines.

Salofalk rectal foam contains propylene glycol, sodium metabisulphite and cetostearyl alcohol

This medicine contains 3.44 g propylene glycol in each actuation of Salofalk rectal foam, which may cause skin irritation.

Sodium metabisulphite may rarely cause severe hypersensitivity reactions and bronchospasm (can be experienced in the form of breathing problems).

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3. How to use Salofalk rectal foam

Always use Salofalk rectal foam exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration:

This medicine may only be used rectally, so it has to be inserted through the anus. It is *not intended to be taken by mouth*. Do not swallow.

Dosage:

Dose for adults:

The usual dose is 2 spray actuations once a day at bedtime. If you have difficulty retaining this amount of foam, it may also be administered in two separate doses: one at bedtime and the other during the night or early in the morning (after excreting the first dose).

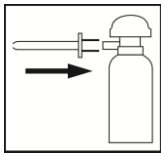
Emptying your bowels before using Salofalk rectal foam produces the best results.

Use in children:

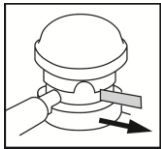
Salofalk rectal foam should not be used in children because there is little experience and only limited documentation for an effect in children.

Preparing to use the foam

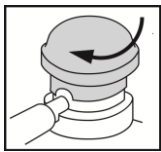
Store and use Salofalk rectal foam at room temperature (between 20 and 30°C). Do not refrigerate or freeze. Also see section 5.



Push the applicator firmly onto the spout of the spray can.
Shake the spray can for about 20 seconds to mix the contents.

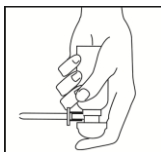


Before first use, remove the safety lock (plastic flap) from under the pump dome.

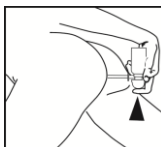


Twist the dome on the top of the spray can until the semi-circular gap underneath is in line with the applicator. The spray can is now ready for use.

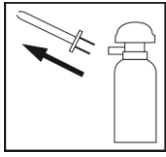
Using the foam



Place your index finger on the top of pump dome and turn the can upside down. Note that the spray can will only work properly when held with the pump dome pointing down.



Stand with one foot on a stool or chair or lie on your side with the lower leg stretched out and the upper leg bent for balance.
Insert the applicator into your rectum as far as possible. Push the pump dome down fully once and then **slowly** release it – the foam comes out of the spray can when you release the dome. To administer the second spray, push the dome again and release slowly. Keep the applicator in place for 10-15 seconds before taking it out. This ensures the full dose is delivered into the rectum and no foam is spilt.



After administering the foam, remove the applicator and dispose of it with your household waste in the plastic bag provided. Use a new applicator for the next administration.

- Wash your hands and try not to empty your bowels until the next morning.
- If you go to hospital or see another doctor, tell them you are using this medicine.

Use Salofalk rectal foam regularly and consistently to achieve the desired effect.

Duration of treatment

How long you will use the medicine depends upon your condition. Your doctor will decide how long you are to continue the medication.

Mild acute episodes of inflammatory bowel disease (ulcerative colitis) generally subside after 4-6 weeks. If long-term treatment is required, your doctor will prescribe you an oral form of mesalazine, e.g. Salofalk granules.

If you think that the effect of Salofalk rectal foam is too strong or too weak, talk to your doctor.

If you use more Salofalk rectal foam than you should

Contact a doctor if you are in doubt so he or she can decide what to do.

If you use too much Salofalk rectal foam on one occasion, just take your next dose as prescribed. Do not use a smaller amount.

If you forget to use Salofalk rectal foam

Do not take a larger than normal dose of Salofalk rectal foam next time, but continue treatment at the prescribed dosage.

If you stop using Salofalk rectal foam

Do not stop using this product until you have talked to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Salofalk rectal foam can cause side effects, although not everybody gets them.

If you experience any of the following symptoms after using this medicine, you should contact your doctor and stop using Salofalk rectal foam immediately:

- **General allergic reactions** such as skin rash, fever, joint pain and/or breathing difficulties or a general inflammation of your large bowel (causing severe diarrhoea and abdominal pain). These reactions are very rare.
- A marked reduction of your general health, especially if accompanied by fever, and/or a sore throat and mouth. These symptoms can, very rarely, be due to a fall in the number of white cells in your blood, which may make you more prone to developing a serious infection (**agranulocytosis**). Other cells of the blood may also be affected (e.g. platelets or red cells causing **aplastic anaemia or thrombocytopenia**) and cause symptoms which may include unexplained bleeding, purple spots or patches under your skin, anaemia (feeling tired, weak and looking pale, especially

on lips and nails). A blood test can confirm whether your symptoms are due to an effect of this medicine on your blood. These reactions are very rare.

- **Serious skin rashes** with reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, wide-spread rash, fever and enlarged lymph nodes. These can be preceded by fever and flu-like symptoms. These reactions occur in an unknown number of patients (frequency not known).
- Shortness of breath, chest pain or irregular heartbeat, or swollen limbs which may be indicative of **cardiac hypersensitivity reactions**. These reactions are rare.
- **Problems with your kidney function** (can occur very rarely), e.g. a change in the colour or amount of urine produced and swollen limbs or a sudden flank pain (caused by a kidney stone) (occur in an unknown number of patients (frequency not known)).
- **Strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears**. These could be symptoms of increased pressure within your skull (idiopathic intracranial hypertension) (frequency not known [cannot be estimated from the available data]).

The following side effects have also been reported by patients using mesalazine:

Common: may affect less than 1 in 10 patients

- Abdominal discomfort.
- Rash, itching

Uncommon: may affect less than 1 in 100 patients

- Anal discomfort, anal irritation and painful urgent need to empty the bowels.

Rare: may affect less than 1 in 1,000 patients

- Abdominal pain, diarrhoea, wind (flatulence), nausea and vomiting
- Headache, dizziness
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)

Very rare: may affect less than 1 in 10,000 patients

- Severe abdominal pain, because of acute inflammation of the pancreas
- Shortness of breath, cough, wheezing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions
- Muscle and joint pain
- Jaundice or abdominal pain because of liver and bile flow disorders
- Hair loss and the development of baldness
- Numbness and tingling in the hands and feet (peripheral neuropathy)
- Reversible decrease in semen production

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Salofalk rectal foam

Keep this medicine out of the sight and reach of children.

Do not use Salofalk rectal foam after the expiry date which is stated on the carton and the spray can. The expiry date refers to the last day of that month.

The contents of the container must be used within 12 weeks after first opening.

Do not store above 30°C.

Do not refrigerate or freeze.

Note: foam may cause staining.

The container is pressurised and contains 3.75% by weight of flammable propellant. Protect from sunlight and temperatures over 50°C. Do not force open, pierce or burn empty containers, even after use. Do not spray near a flame or incandescent material.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Salofalk rectal foam contains

The active substance of Salofalk rectal foam is mesalazine and each spray actuation contains 1 g of mesalazine.

The other ingredients are sodium metabisulphite (E223), disodium edetate, cetostearyl alcohol, polysorbate 60, propylene glycol and propane, n-butane, isobutane as propellants.

What Salofalk rectal foam looks like and contents of the pack

Salofalk rectal foam is a white-greyish to slightly reddish-violet and creamy firm foam.

Salofalk rectal foam is available in packs containing 1 spray can and 14 applicators and as a bundle pack. A bundle pack consists of 4 packs containing 1 spray can and 14 applicators each. Each spray can of Salofalk rectal foam contains 80 grams of foam, which is sufficient for 14 spray actuations (equivalent to 7 doses).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Salofalk rectal foam is authorised in the Member States of the EEA under the following name: Austria, Denmark, Finland, Germany, Great Britain, Greece, Ireland, Luxembourg, The Netherlands, Norway, Portugal, Spain and Sweden: Salofalk®

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