SALOFALK® foam

Mesalazine

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SALOFALK foam?

SALOFALK foam contains the active ingredient mesalazine (5-aminosalicylic acid). SALOFALK foam is used to treat and prevent relapses of mild to moderate attacks of ulcerative colitis (inflammation of the large bowel).
For more information, see Section 1. Why am I using SALOFALK foam? in the full CMI.

2. What should I know before I use SALOFALK foam?

Do not use if you have ever had an allergic reaction to SALOFALK foam or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I use SALOFALK foam? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SALOFALK foam and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use SALOFALK foam?

- The usual dose is of SALOFALK foam is two applications once daily at bedtime, although your doctor or pharmacist will tell you exactly how much to use and where to find this information.
- This medicine may only be used rectally, so it has to be inserted through the anus. Do NOT take it by mouth.

More instructions can be found in Section 4. How do I use SALOFALK foam? in the full CMI.

5. What should I know while using SALOFALK foam?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using SALOFALK foam. • Remind them if any new medicines are about to be started.
Things you should not do	• Do not use SALOFALK foam to treat any complaint other than that directed by your doctor. It may not be safe to use SALOFALK foam for another complaint. • Do not give SALOFALK foam to someone else even if their symptoms are the same. It may not be safe for another person to use SALOFALK foam.
Driving or using machines	• This medicine is not expected to affect your ability to drive a car or operate machinery. • However, you should still be careful before you drive or use any machines or tools until you know how SALOFALK foam affects you. SALOFALK foam may cause dizziness in some people.
Looking after your medicine	• Keep SALOFALK foam in a cool dry place, protected from light, where the temperature stays below 25°C. • Do not refrigerate or freeze. • Keep away from flames or sparks including cigarettes, SALOFALK foam contains flammable gas. Heat and dampness can destroy some medicines including SALOFALK foam. • Keep it where children cannot reach it. • A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

For more information, see Section 5. What should I know while using SALOFALK foam? In the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually mild and temporary. The most common side effects using SALOFALK foam are: headache, mild stomach pains, excessive gas in the stomach or bowel, increased number of bowel motions, diarrhoea, nausea and vomiting, rash or itchy skin. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? In the full CMI.

SALOFALK® foam

Active ingredient: mesalazine

Consumer Medicine Information (CMI)

This leaflet provides important information about using SALOFALK foam. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SALOFALK foam.**

Where to find information in this leaflet:

1. Why am I using SALOFALK foam?
2. What should I know before I use SALOFALK foam?
3. What if I am taking other medicines?
4. How do I use SALOFALK foam?
5. What should I know while using SALOFALK foam?
6. Are there any side effects?
7. Product details

1. Why am I using SALOFALK foam?

SALOFALK foam contains the active ingredient mesalazine (5-aminosalicylic acid). Mesalazine is an anti-inflammatory agent used to treat inflammatory bowel disease.

SALOFALK foam is used to treat and prevent relapses of mild to moderate attacks of ulcerative colitis (inflammation of the bowel).

Ask your doctor if you have any questions about why SALOFALK foam has been prescribed for you.

Your doctor may have prescribed SALOFALK foam for another reason.

Do not give SALOFALK foam to a child below 12 years of age. The safety and effectiveness of SALOFALK foam in this group have not been established.

2. What should I know before I use SALOFALK foam?

Warnings

SALOFALK foam is not addictive.

Do not use SALOFALK foam if:

- you are allergic to mesalazine, to salicylates such as acetylsalicylic acid (e.g. Aspirin®) or any of the ingredients listed at the end of this leaflet. Signs of allergic reactions may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- you suffer from a severe kidney or liver problem.
- the expiry date (EXP) printed on the pack has passed. If you use this medicine after the expiry date has passed, it may not work as well.
- the product package is torn or shows signs of tampering.
- Always check the ingredients to make sure you can use this medicine. If unsure, speak to your doctor or pharmacist.

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes.
- have or have had any other medical conditions, especially lung or breathing problems such as asthma. SALOFALK foam contains sulfite which may cause an allergic reaction
- have kidney problems. Kidney stones may develop with use of mesalazine, the active ingredient in SALOFALK foam. Symptoms may include pain in the side of abdomen and blood in urine. Take care to drink sufficient amounts of liquid during treatment with SALOFALK foam.
- have liver problems.
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

If you have not told your doctor about any of the above, tell them before you start to use SALOFALK foam.

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

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

SALOFALK foam contains propylene glycol which may cause skin irritation in some people. In addition, propylene glycol may cause drowsiness and confusion in people with kidney problems.

SALOFALK foam also contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

People who take medicines containing mesalazine, such as SALOFALK foam, may notice red-brown discolouration in the toilet bowl. This is due to mesalazine in urine of these people coming in contact with sodium hypochlorite bleach used to clean the toilet. This is the result of a chemical reaction between mesalazine and bleach and is harmless.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. SALOFALK foam should not be used during breastfeeding as there is no experience using it in breastfeeding women.

Your doctor will discuss the risks and benefits of using SALOFALK foam if you are pregnant or breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

SALOFALK foam may interfere with the action of the following types of medicines:

- anticoagulants which are medicines used to stop blood clots, e.g. warfarin.

Some medicines may interfere with SALOFALK and affect how it works.

- glucocorticoids which are medicines used to treat inflammation or swelling, e.g. prednisolone
- sulphonylureas which are medicines used to lower blood sugar
- methotrexate which is a medicine used to treat some types of cancer and arthritis.
- probenecid/sulphinpyrazone which are medicines used to treat gout
- spironolactone/frusemide which are medicines which lower blood pressure or increase volume of urine
- rifampicin which is a medicine used to treat tuberculosis
- azathioprine which is a medicine used to suppress the immune system
- mercaptopurine or thioguanine which are medicines used to treat leukaemia.

You may need to use different amounts of the above medicines, or you may need to take different medicines when you are using SALOFALK foam. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SALOFALK foam.

4. How do I use SALOFALK foam?

How much to use

Follow all directions given to you by your doctor or your pharmacist carefully.

They may differ from the information contained in this leaflet.

- The usual dose of SALOFALK foam is two applications once daily at bedtime, although the doctor or pharmacist will tell you exactly how much to use and where to find this information.
- Each SALOFALK foam can contains 80 g of foam which delivers a total of 14 applications, with each application delivering 1g of mesalazine. If your doctor prescribed a dose of 1g/day, you will need to administer one (1) application each day. Alternatively, if your doctor prescribed a dose of 2g/day, you will need to administer two (2) applications each day.

When to use SALOFALK foam

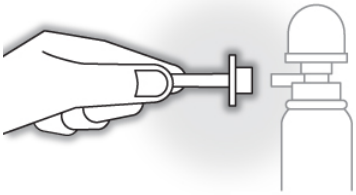
- SALOFALK foam should be used each evening at bedtime.

How to use SALOFALK foam

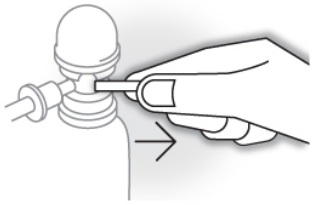
If possible, go to the toilet and empty your bowels before using SALOFALK foam.

Store and use SALOFALK foam at room temperature, 20 - 25°C (see also section on storage).

1. Wash your hands thoroughly with soap and water.
2. Push the applicator firmly onto the spout of the aerosol can.

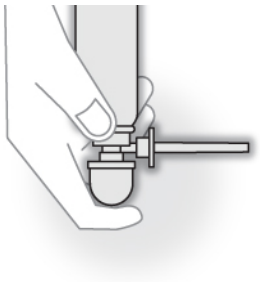


3. Shake the can for 15 seconds each time before use.
4. Each time you use a new can, remove the safety tab from under the pump dome at the top of the aerosol can.

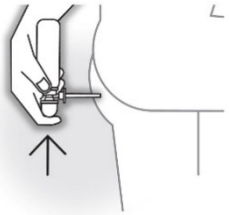


5. Each time you use a new can, twist the pump dome in a clockwise direction until the semi-circular gap underneath it is in line with the nozzle. It is now ready to use.

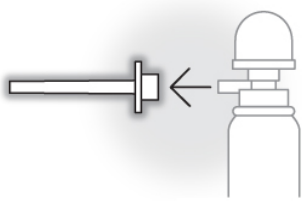
6. Place your forefinger on top of the pump dome. Turn the aerosol can upside down and keep it upright with the pump dome **pointing down for it to work properly.**



7. Stand with one foot on the floor and raise the other foot onto a chair or stool.



8. Insert the applicator into the rectum as far as is comfortable. To administer SALOFALK foam, push the pump dome in fully once with your index finger and hold for 5 seconds, to prime the aerosol can and then very slowly lift your finger off the pump dome. The foam containing 1 g of mesalazine is now being delivered and you must wait 15 seconds for the dosing to be completed.
   If you doctor has prescribed 2 g of mesalazine/day, keep the applicator in place and repeat the above process.
9. Wait a further 15 seconds before slowly withdrawing the applicator from the rectum to allow any residual foam to be released. This is important to reduce the risk of local irritation around your anus.
10. Remove the applicator from the spout of the aerosol can and dispose of it in the plastic bag provided as domestic waste.



11. Wash your hands thoroughly and try not to empty your bowels again until the next morning.

You may experience a little discomfort and a feeling of urgency to empty your bowels immediately after the foam insertion. This is normal and expected due to the inflammation present within the bowel. Try to resist this urge to empty your bowels for as long as possible. This feeling will subside as treatment continues and the inflammation decreases.

The following QR code links to a patient instructions for use video, which covers the same dosing procedure detailed above:

How long to use SALOFALK foam

Continue using your SALOFALK foam for as long as your doctor tells you.

This medicine helps control your condition but does not cure it. It is important to keep using your SALOFALK foam for as long as your doctor tells you, even if you feel well.

If you forget to use SALOFALK foam

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. If you are not sure what to do, ask your doctor or pharmacist.

If you use too much SALOFALK foam

If you think that you have used too much SALOFALK foam, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**) for advice, or
- contact your doctor, or
- go to the Accident & Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Possible symptoms of overdose may include feeling sick, vomiting and diarrhoea.

5. What should I know while using SALOFALK foam?

Things you should do

Make sure that all of your doctors and pharmacists who are treating you know you are using SALOFALK foam. Remind them if any new medicines are about to be started.

Tell your doctor immediately if you become pregnant or if you wish to breastfeed while using SALOFALK foam.

Things you should not do

- Do not use SALOFALK foam to treat any complaint other than that directed by your doctor. It may not be safe to use SALOFALK foam for another complaint.

- Do not give SALOFALK foam to someone else even if their symptoms are the same. It may not be safe for another person to use SALOFALK foam.
- Do not change the dosage without checking with your doctor.

Driving or using machines

This medicine is not expected to affect your ability to drive a car or operate machinery. **However, you should be careful before you drive or use any machines or tools until you know how SALOFALK foam affects you.**

SALOFALK foam may cause dizziness in some people.

Looking after your medicine

- Keep SALOFALK foam in a cool dry place, protected from light, where the temperature stays below 25°C.
- Do not refrigerate or freeze.
- Keep away from flames or sparks including cigarettes, SALOFALK foam contains flammable gas. Heat and dampness can destroy some medicines including SALOFALK foam.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

Use SALOFALK foam within 12 weeks of first opening.

Getting rid of any unwanted medicine

Do not pierce or burn the SALOFALK foam can even when empty.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• headache • mild stomach pain • excessive gas in the stomach or bowel • abdominal discomfort • diarrhoea • anal discomfort • anal irritation • painful feeling of incomplete emptying of the bowel • increased number of bowel motions • nausea (feeling sick) • rash or itchy skin • dizziness • common cold • fever, muscle aches and pains, painful joints and chest pain (sometimes spreading to the neck and shoulders, and sometimes fever) • mild skin rash, itching or hives • numbness, tingling or weakness of the arms and legs • pain in the upper belly (may be due to inflammation of the pancreas) • worsening of ulcerative colitis.	**Speak to your doctor if you have any of these mild effects and they worry you.**

Serious side effects

Serious side effects	What to do
• **general allergic reaction** 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) • marked reduction of general health, especially if accompanied by fever and/or sore throat or mouth. Very rarely this can be due to a low white blood cell count (**agranulocytosis**), which may increase the risk of developing a serious infection. Other blood cells may also be affected (e.g. platelets or red cells causing **aplastic anaemia** or **thrombocytopenia**) with symptoms which may include unexplained bleeding, purple spots or patches under your skin especially on lips and nails, anaemia (feeling tired, weak and looking pale,). A blood test can confirm whether your symptoms are due to this medicine. These reactions are very rare. • **Serious skin rashes** with reddish non-elevated, target-like or circular patches on the trunk,	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, widespread 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). • **Strong or recurrent headache, disturbed vision, or ringing or buzzing in ears.** These could be symptoms of increased pressure within your skull (idiopatic intracranial hypertension). These reactions occur in an unknown number of patients (frequency not known (cannot be estimated from available data)). • 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)). As a precaution, your doctor may have your blood, liver and kidney tested regularly during treatment with this medicine. **Other rare events, which have been reported with mesalazine include:** • changes in liver function tests • liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, abdominal pain, fever, itching, yellowing of the skin and eyes, and dark coloured urine • allergic, inflammatory or other lung conditions • shortness of breath, difficulty breathing, cough, wheezing, chest pain that worsens when breathing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions. • increased sensitivity of the skin to sun and ultraviolet light (photosensitivity)	

Serious side effects	What to do
• reversible decrease in semen production (oligospermia) • hair loss and the development of baldness (alopecia)	

As a precaution, your doctor may have your blood, liver and kidney tested regularly during treatment with SALOFALK foam.

Tell your doctor or pharmacist if you notice anything which is unusual, including anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking/using any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SALOFALK foam contains

Active ingredient (main ingredient)	**1 g mesalazine in each application**
Other ingredients (inactive ingredients)	• Sodium metabisulfite • polysorbate 60 • cetostearyl alcohol • disodium edetate • propylene glycol • propane • butane • isobutane.

Do not take this medicine if you are allergic to any of these ingredients.

What SALOFALK foam looks like

SALOFALK foam is a greyish white to slightly reddish violet, creamy firm foam.

SALOFALK foam carton includes one (1) aerosol can, containing 80 g of foam, 14 applicators for the administration of the foam and 14 plastic bags to dispose of each applicator.

This provides flexibility based on your doctor's prescription. If the prescribed dose is 1g/day, you will use all 14 applicators (a new one each day) over 2 weeks. If the

prescribed dose is 2g/day, you will need to administer two (2) doses with one applicator each day. Therefore, you would only need 7 applicators and you can discard the 7 unused applicators with the used can.

Who distributes SALOFALK foam

Dr Falk Pharma Australia Pty Ltd
9 Help Street
Chatswood, NSW 2067

Australia

Australian Registration Number: AUST R 95960

SALOFALK® is a registered trademark of Dr. Falk Pharma GmbH, Germany.

This leaflet was prepared in March 2025.