

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SALOFALK foam. It does not contain all of the available information. Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the possible risks of using SALOFALK foam against the expected benefits.

Ask your doctor or pharmacist if you have any concerns about using SALOFALK foam.

Keep this leaflet with the medicine.

You may want to read it again.

What SALOFALK foam is used for

SALOFALK foam contains the active ingredient, mesalazine (5-aminosalicylic acid), which is used to treat, and prevent relapses of mild to moderate attacks of ulcerative colitis (inflammation of the large 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.

SALOFALK foam is not addictive.

SALOFALK foam is only available on a doctor's prescription.

Before you use it

When you must not use it

Do not use SALOFALK foam if:

- you are allergic to mesalazine or aspirin-like medicines, sulfites 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 package is torn or shows signs of tampering.

Do not give SALOFALK foam to a child 12 years old or under.

The safety and effectiveness of SALOFALK foam in this age group has not been established.

Talk to your doctor if you are not sure whether you should start to use SALOFALK foam.

Before you start to use it

Tell your doctor if:

- **you have any allergies to any other medicines, foods, preservatives or dyes.**
- **you are pregnant or intend to become pregnant.**
Your doctor will discuss the risks and benefits of using SALOFALK foam if you are pregnant.
- **you are breastfeeding or wish to breastfeed.**

SALOFALK foam should not be used during breastfeeding as there is no experience using it in breastfeeding women.

Women using SALOFALK foam and who are breastfeeding or wish to breastfeed should discuss this with their doctor.

- **you have or had any medical conditions, especially lung or breathing problems such as asthma.**
SALOFALK foam contains a sulfite which may cause an allergic reaction and 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).
- **you have kidney problems**
Kidney stones may develop with use of mesalazine, such as SALOFALK foam. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with SALOFALK foam.
- **you have liver problems.**
- **you 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 Stevens-Johnson syndrome, toxic epidermal necrolysis 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, as described in Side effects section below.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any 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 - medicines used to stop blood clots, e.g. warfarin
- glucocorticoids - medicines used to treat inflammation or swelling (e.g. prednisolone)
- sulphonylureas - medicines used to lower blood sugar
- methotrexate - medicine used to treat some types of cancer and arthritis
- probenecid/sulphinpyrazone - medicines used to treat gout
- spironolactone/frusemide - medicines which lower blood pressure or increase volume of urine
- rifampicin - a medicine used to treat tuberculosis
- azathioprine - a medicine used to suppress the immune system

- mercaptopurine or thioguanine - medicines used to treat leukaemia.

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

How to use it

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

They may differ from the information contained in this leaflet.

How much to use

The usual dose 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.

Each SALOFALK foam can contains 80g of foam which is delivers 14 applications, or 7 days dosing (2 applications/ dose).

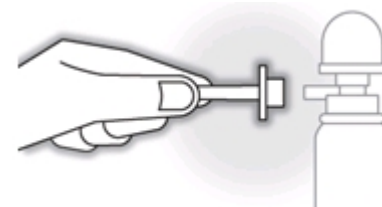
Two applications are equivalent to 2 g mesalazine.

How to use it

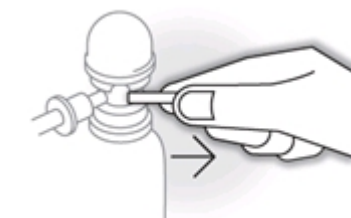
If possible, go to the toilet and empty your bowels before using SALOFALK foam.

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.
4. Each time you use a new can, remove the safety tab from under the pump dome.

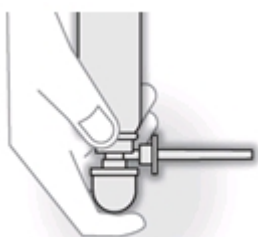


5. Twist the dome on top of the canister until the semi-circular gap underneath it is in line with the nozzle.

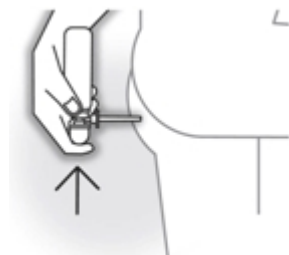


The aerosol can is now ready for use

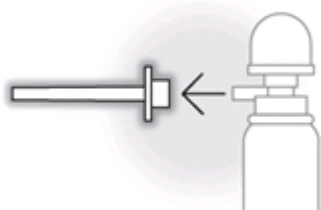
6. Place your forefinger on top of the pump dome. Turn the aerosol can upside down and keep it upright with the pump dome pointing down for it to work properly.



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 the **first application** of SALOFALK foam (equivalent to 1 g mesalazine), push the pump dome fully once with your index finger and hold for 5 seconds and then very slowly lift your finger off the pump dome. The foam is being delivered at this time and you must wait 15 seconds for the dosing to be completed.
- To administer the **second application**, keep the applicator in place and repeat the above process.
9. Wait a further 30 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 rectum.
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.

How long to use it

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

This medicine helps to control your condition, but does not cure it. It is important

to keep taking your SALOFALK foam even if you feel well.

If you forget to use it

If you forget to use SALOFALK leave out that dose completely.

Use your next dose at the normal time it is due.

Do not use a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have used too much SALOFALK foam. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are using it

Things you must do

Make sure that all 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 while using SALOFALK foam.

Things that you must not do

Do not use SALOFALK foam to treat any other complaint than that directed by your doctor.

It may not be safe to use SALOFALK foam for another complaint.

Do not give SALOFALK foam to anyone else even if they have the same condition as you.

It may not be safe for another person to use SALOFALK foam.

Do not change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how SALOFALK foam affects you.

SALOFALK foam generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, SALOFALK foam may cause dizziness or light-headedness in some people. Make sure you know how you react to SALOFALK foam before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using SALOFALK foam.

Like all medicines, SALOFALK foam may have some side effects. Most side effects are mild and may disappear without stopping this medicine. However, some may be serious and need medical attention.

Mild effects:

Tell your doctor or pharmacist if you notice any of the following that are troublesome or ongoing:

- 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.

More serious effects:

Tell your doctor immediately if you notice any of the following:

- fever, muscle aches and pains, painful joints and chest pain (sometimes spreading to the neck and shoulders, and sometimes associated with fever)
- mild skin rash, itching or hives
- numbness or weakness of the arms and legs
- pain in the upper belly (may be due to inflammation of the pancreas)
- worsening of ulcerative colitis.

Stop using SALOFALK foam and contact your doctor or go to the Accident and Emergency department of your nearest hospital if any of the following happens:

- allergic reaction including swelling of limbs, face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- marked worsening 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.
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and/or eyes. These serious skin rashes can be preceded by fever and flu-like symptoms.

Other rare events, which have been reported with mesalazine, include:

- changes in kidney function and inflammation of the kidney
- changes in blood test results such as low white blood cell and/or platelet counts
- changes in liver function tests
- liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine
- changes relating to your heart
- allergic, inflammatory or other lung conditions
- shortness of breath, difficulty breathing, cough, wheezing, chest pain that worsens when breathing

- increased sensitivity of the skin to sun and ultraviolet light (photosensitivity)
- reversible decrease in semen production (oligospermia)
- hair loss and the development of baldness (alopecia)
- severe diarrhoea and abdominal pain due to an allergic reaction to this medicine (pancolitis).

Other events with unknown frequency, include:

- kidney stones and associated kidney pain

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

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

Keep SALOFALK foam in a cool dry place, protected from direct sunlight, where the temperature stays below 25°C.

Do not refrigerate or freeze.

Keep away from flames or sparks including cigarettes.

SALOFALK foam contains a flammable gas.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines, including SALOFALK foam.

Keep SALOFALK foam 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.

Use SALOFALK foam within 12 weeks of first opening.

Disposal

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

If your doctor tells you to stop using SALOFALK foam, ask your pharmacist what to do with any foam that is left over.

Product description

What it looks like

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

SALOFALK foam is supplied in an aerosol can, containing 80 g of foam, with 14 disposable applicators for the administration of the foam sufficient for 14 applications (2 applications/dose).

Ingredients

Each application of SALOFALK foam contains 1 g of the active ingredient, mesalazine.

SALOFALK foam also contains:

- sodium metabisulfite
- polysorbate 60
- cetostearyl alcohol
- disodium edetate
- propylene glycol
- propane

- butane
- isobutane.

Sponsor

Dr Falk Pharma Australia Pty Ltd, 815 Pacific Highway, Chatswood, NSW 2067

Australian Registration Number: AUST R 95960

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

This leaflet was revised in December 2020.