

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SALOFALK. 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 against the expected benefits.

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

Keep this leaflet with the medicine.

You may want to read it again.

What SALOFALK is used for

SALOFALK enemas contain 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 enemas have been prescribed for you.

Your doctor may have prescribed SALOFALK for another reason.

SALOFALK is not addictive.

SALOFALK is not expected to affect your ability to drive a car or operate machinery.

SALOFALK is only available on a doctor's prescription.

Before you use it

When you must not use it

Do not use SALOFALK if:

- you are allergic to mesalazine or aspirin-like medicines, 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 to a child below 12 years of age.

The safety and effectiveness of SALOFALK in this group have not been established.

Before you start to use it

Tell your doctor if:

- **you have any allergies**
- **you are pregnant or intend to become pregnant or are breastfeeding or wish to breastfeed.** Your doctor will discuss the risks and benefits of using SALOFALK if you are pregnant or breastfeeding.
- **you have or have had any medical conditions, especially lung or breathing problems such as asthma.** SALOFALK contains a sulfite which may cause an allergic reaction.

- **you have kidney problems**
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.
- **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.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis 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 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 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, eg. 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, medicine used to treat tuberculosis
- azathioprine, 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. Your doctor or pharmacist will advise you.

Salofalk 2g/30ml enemas contain potassium metabisulphite and sodium benzoate

This medicine contains potassium metabisulphite. It may therefore cause allergic reactions like allergic shock and bronchial constriction (bronchospasm) particularly if you suffer from asthma or have a history of allergies.

Salofalk enemas also contain sodium benzoate which may provoke hypersensitivity reactions like irritation of the skin, eyes and mucous membranes.

How to use it

How much to use

The usual dose is one enema a day at bedtime, although the doctor or pharmacist will tell you exactly how much to use and where to check this information.

How to use it

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

1. Wash your hands thoroughly with soap and water.
2. Using a pair of scissors carefully cut along the dotted line of the pack containing the enema bottle. Take care not to cut or damage the bottle.
3. Shake the enema bottle for 30 seconds.
4. Remove the protective cap from the applicator and hold the bottle by its upper end.
5. Lie down on your left side with the left leg outstretched and the right leg bent.



Guide the applicator deep into the rectum and whilst holding the bottle obliquely, squeeze slowly.



6. Remove the applicator from the rectum when the bottle is empty.
7. Remain lying down for at least 30 minutes to allow the enema to spread throughout the lower part of the large intestine.



8. 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 enema 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

SALOFALK helps control your condition but does not cure it.

Therefore, you must use it for as long as your doctor tells you to.

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 have trouble remembering when to use SALOFALK, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used too many SALOFALK enemas.

Do this even if there are no signs of discomfort or poisoning.

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

While you are using it

Things you must do

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

Things that you must not do

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

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

Do not give SALOFALK to someone else even if their symptoms are the same.

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

Side effects

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

Like all medicines, SALOFALK may have some side effects. Most side effects are mild and may disappear without stopping SALOFALK. 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 pains
- excessive gas in the stomach or bowel
- increased number of bowel motions
- diarrhoea
- 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 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 and contact your doctor or go to Accident and Emergency at 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 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.

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 enemas in their original package until it is time to use them.

If you take them out of their packaging, they may not keep well.

Keep SALOFALK in a cool dry place, protected from light, where the temperature stays below 30°C.

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.

Keep SALOFALK where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

SALOFALK enemas are a very light tan to brown suspension.

They are available in plastic squeeze bottles in individual blister packs.

Available in packs of 7 enemas.

Ingredients

Each SALOFALK enema contains either 2.0 g or 4.0 g of the active ingredient, mesalazine.

They also contain the following inactive ingredients:

- carbomer 934P
- disodium edetate
- potassium acetate
- potassium metabisulphite
- sodium benzoate
- xanthan gum
- water- purified.

Sponsor

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

SALOFALK enemas Australian Registration Numbers:

2 g/30 mL: AUST R 80651

2 g/60 mL: AUST R 80653

4 g/60 mL: AUST R 80652.

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

This leaflet was revised in December 2020.