

SALOFALK[®] suppository

mesalazine

Consumer Medicine Information (CMI)

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 suppositories contain the active ingredient, mesalazine (5-aminosalicylic acid) and are used to treat inflammatory bowel disease limited to the rectum.

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

Your doctor may have prescribed it 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 has 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**
- **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, 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, 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 use different medicines when you are using SALOFALK. 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

Use one SALOFALK 1 g suppository once a day at bedtime.

How to use it

This medicine may only be administered into the back passage (rectum) therefore the

suppository has to be inserted through the anus.

Do not swallow.

It is not intended to be used by mouth.

Directions for use:

1. Empty your bowels if necessary and wash your hands.
2. Remove a suppository from the plastic strip.
3. Lie down on your left side with the left leg outstretched and the right leg bent.
4. Gently insert the suppository – pointed end first, into the rectum and then try to remain lying on your left side for one hour as this will aid the action of the suppositories.
5. Wash your hands again.

When to use it

SALOFALK 1 g suppositories should be administered preferably at bedtime.

Use SALOFALK the same time each day.

This will help you remember when to use it.

How long to use it

SALOFALK helps control your condition but does not cure it. Therefore, you must continue to use SALOFALK for as long as your doctor tells you to.

If you forget to use it

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

Administer 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 many SALOFALK suppositories.

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

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. Remind them if any new medicines are about to be started.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

It may affect other medicines used during surgery.

Tell your doctor immediately if you become pregnant while using this medicine.

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 your medicine to anyone else, even if they have the same condition as you.

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

Do not stop using your SALOFALK or change the dosage without checking with your doctor.

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 this medicine. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

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
- constipation
- 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.

Tell your doctor immediately 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 or pharmacist 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 in the original package until it is time to use them.

If you remove the suppositories out of their packaging, they may not keep as well.

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

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

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 or the expiry date has passed, ask your pharmacist what to do with any suppositories that are left over.

Product description

What it looks like

SALOFALK 1 g are light beige coloured, torpedo-shaped suppositories in white plastic strip packs.

Available in packs of 30.

Ingredients

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

Each SALOFALK suppository also contains hard fat.

Sponsor

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

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