SALOFALK® SUPPOSITORIES Mesalazine

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.

Please read this leaflet before you start using SALOFALK.

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

If you have any concerns about using SALOFALK, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What SALOFALK is used for

SALOFALK contains an ingredient called mesalazine (5-aminosalicylic acid), which is used to treat inflammatory bowel disease. SALOFALK suppositories are used for inflammatory disease limited to the rectum.

Your doctor may have prescribed SALOFALK for another use. Ask your doctor if you have any questions about why SALOFALK has been prescribed for you.

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 SALOFALK

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:

1. **You have any allergies.**

2. **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.

3. **You have or have had any medical conditions, especially the following:**

- Lung or breathing problems such as asthma.

If you have not told your doctor about any of the above, tell him/her before you use SALOFALK.

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.
- 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, medicine 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 SALOFALK

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. It is not intended to be used by mouth. Do not swallow.

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. 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.
4. Wash your hands again.

When to use it

Salofalk 1g Suppositories should be administered preferably at bedtime.

Use SALOFALK the same time each day. This will help you remember when to use SALOFALK.

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 SALOFALK

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

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 SALOFALK

Things you must do

Make sure that all of your doctors and pharmacists 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 taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

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 SALOFALK. However, some may be serious and need medical attention.

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

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
- 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

If any of the following happens, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Allergic reaction including swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing

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

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

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

After using SALOFALK

Storage

- Keep your SALOFALK in their original package until it is time to use them. If you remove them out of their packaging, they may not keep well.
- Keep your SALOFALK in a cool dry place where the temperature stays below 25°C.
- Do not store SALOFALK or any other medicine in the bathroom or near a sink.
- Do not leave SALOFALK 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 1g Suppositories are light beige coloured, torpedo-shaped suppositories in white plastic strip packs.

Ingredients

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

Each SALOFALK suppository also contains hard fat.

SALOFALK 1 g suppositories are available in packs of 30 suppositories.

Manufacturer/Supplier

SALOFALK suppositories are made in Germany by:

Dr. Falk Pharma GmbH
Leinenweberstr. 5
D-79041 Freiburg, Germany

and are supplied in Australia by:

Orphan Australia Pty. Ltd.
300 Frankston-Dandenong Road
Dandenong
Victoria 3175.
www.orphan.com.au

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