

**SALOFALK® ENEMAS**  
**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. If you are helping someone else use SALOFALK, please read the leaflet before you give the first dose.

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, and protect against, mild to moderate attacks of ulcerative colitis (inflammation of the large bowel).

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.
- You have or have had stomach or duodenal ulcer
- You have or have had problems with the clotting of your blood or you tend to bleed easily.
- 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 12 years old and under. The safety and effectiveness of Salofalk in this age 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. Salofalk contains a sulfite which may cause an allergic reaction.

**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, medicine 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 take different medicines when you are using SALOFALK. Your doctor or pharmacist will advise you.

---

**How to use SALOFALK**

---

***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. Shake the enema bottle for 30 seconds.
3. Remove the protective cap from the applicator and hold the bottle by its upper end.
4. Lie down on your left side with the left leg outstretched and the right leg bent.
5. 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.

***How long to use it***

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

***If you forget to use SALOFALK***

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.

### **Overdose**

Telephone your doctor or Poisons Information Centre (13 11 26) or go to casualty at your nearest hospital immediately if you think that you or anyone else may have used too many SALOFALK enemas, even if there are no signs of discomfort or poisoning.

Possible symptoms may include feeling sick, vomiting and diarrhoea.

---

### **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.

#### **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.

SALOFALK should only be used by the person for whom it was prescribed. Do not give SALOFALK to someone else even if his/her 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 taking 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
- 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 the 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 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 if you notice anything else that is making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

### **After using SALOFALK**

---

### **Storage**

---

### **Product description**

---

#### **What it looks like**

SALOFALK enemas are presented as a very light tan to brown, suspension.

#### **Ingredients**

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

SALOFALK enemas also contain the following inactive ingredients:

Carbomer 934, Disodium edetate, Potassium acetate, Potassium metabisulphite, Sodium benzoate, Xanthan gum, purified water.

SALOFALK enemas are available in plastic squeeze bottles in cardboard cartons. Each carton contains 7 enemas in individual blister packs.

- 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 where the temperature stays below 25°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 it. 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.

### **Manufacturer/Supplier**

SALOFALK enemas are made in Germany by:  
Dr. Falk Pharma GmbH  
Leinenweberstrasse. 5  
D-79041 Freiburg, Germany

and are supplied in Australia by:

Orphan Australia Pty. Ltd.  
48 Kangan Driv Berwic Victoria 3806.

This leaflet was prepared in April 2002.

Australian Registration Number:  
SALOFALK enemas 2 g/ 30 mL  
AUST R 80651  
SALOFALK enemas 2 g/ 60 mL  
AUST R 80653  
SALOFALK enemas 4 g/60 mL  
AUST R 80652

SALOFALK® is a trademark of Dr. Falk Pharma GmbH, used under license by Orphan Australia Pty. Ltd.

Draft: 23 April 2002

