

*Consumer Medicine Information***SALOFALK®****SALOFALK® GRANULES**
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 taking SALOFALK.

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

If you have any concerns about taking 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 prevent relapses of, 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 take SALOFALK**When you must not take it**

Do not take 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 group have not been established.

Before you start to take 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 taking 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.
 - Phenylketonuria. Salofalk granules contain aspartame.

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If you have not told your doctor about any of the above, tell him/her before you take 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/furosemide, 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 taking SALOFALK. Your doctor or pharmacist will advise you.

How to take SALOFALK***How much to take*****Granules – Sachet**

For acute ulcerative colitis, the recommended SALOFALK dose is one

500 mg or 1 g sachet three times a day.

For long term treatment of ulcerative colitis, the recommended SALOFALK dose is one 500 mg sachet three times a day.

For some conditions, your doctor may prescribe a different dose.

Granules – Multi-dose Bottle

The multi-dose bottle contains a measuring cap with graduations allowing administration of 500 mg, 1 g and 1.5 g doses of mesalazine.

Measure the amount of granules equivalent to the dose prescribed by your doctor.

See instructions provided at the back of this leaflet.

How to take it

Swallow the SALOFALK granules without chewing with sufficient liquid in the morning, midday and in the evening. Do not crush the granules.

Do not use the multi-dose bottle after 6 months of opening the bottle.

How long to take it

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

If you forget to take SALOFALK

If you forget to take SALOFALK, leave out that dose completely. Take your next dose at the normal time it is due.

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

If you have trouble remembering when to take 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 taken too many SALOFALK granules, even if there are no signs of discomfort or poisoning.

Possible symptoms may include feeling sick, vomiting and diarrhoea.

While you are taking SALOFALK**Things you must do**

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

Things that you must not do

Do not take 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 taken 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 take 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 taking 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

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- 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 taking SALOFALK

Storage

- Keep SALOFALK granules in their original package until it is time to take 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 taking SALOFALK, ask your pharmacist what to do with any granules that are left over.

Product description

What it looks like

SALOFALK granules are presented as greyish white cylindrical to round granules. SALOFALK granules are

available in sachets and multi-dose bottle.

Ingredients

Each SALOFALK sachet contains either 500 mg or 1 g of the active ingredient, mesalazine. Each SALOFALK multi-dose bottle contains 80 g of mesalazine.

SALOFALK sachets and multi-dose bottle also contain the following inactive ingredients:

microcrystalline cellulose, hypromellose, anhydrous colloidal silica, methacrylic acid copolymer, nonoxinol 100, magnesium stearate, simethicone, triethyl citrate, talc, carmellose sodium, aspartame, anhydrous citric acid, vanilla custard flavour 75016-31, povidone, titanium dioxide (E 171)

SALOFALK 500 mg granules are available in packs of 50, 100, or 300 sachets.

SALOFALK 1 g granules are available in packs of 50, 100 or 150 sachets.

SALOFALK multi-dose bottle is available in single units, each with a measuring cap with graduations allowing dispensing of 500 mg, 1 g and 1.5 g doses of mesalazine.

Manufacturer/Supplier

SALOFALK granules 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 Drive
Berwick
Victoria 3806.

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Australian Registration Number:
SALOFALK granules 500 mg sachet
AUST R 80648

SALOFALK granules 1 g sachet
AUST R 80649

SALOFALK granules multi-dose bottle
AUST R 80850

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Pharma GmbH, used under license by
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Instructions for use of the Salofalk multi-dose dispenser bottle



Measuring cap

Rotatable dose dispenser unit with
arrow marking (wedge)

Dose dispenser bottle

A. Preparation of the dose dispenser bottle prior to first use



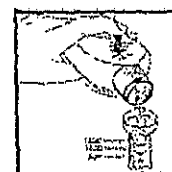
Original seal

Remove measuring cap, remove and discard original seal

B. Dispensing the Salofalk granules



Open the dose dispenser bottle. After a quarter turn, the cap clearly locks into place and the dispenser is fully open (see arrow on the dose dispenser).



Hold the Salofalk multi-dose dispenser bottle in one hand and the measuring cap in the other. By tapping carefully with the finger, dispense the required dose of granules into the measuring cap (lower graduation mark = 500 mg mesalazine, middle graduation mark = 1g mesalazine, upper graduation mark = 1.5 g mesalazine). Pour the measured dose onto a dessertspoon and swallow whole with water.

Seal the dose dispenser bottle by rotating the cap and replacing the measuring cap.