

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 relapse 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.
- 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 6 years of age. 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.

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/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.
- Lactulose or similar preparations, medicines which can change the acidity of the content of the bowels.

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

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 take

Adults and the elderly:

For acute ulcerative colitis, take 1.5 g to 3 g SALOFALK once a day or in 2-3 divided doses.

For long term treatment of ulcerative colitis, take 1.5 g SALOFALK once a day or in 2-3 divided doses.

Children over 6 years old:

The dose of SALOFALK for your child depends on disease severity and body weight. Your doctor should tell you how much SALOFALK your child should take.

For acute ulcerative colitis, give your child 30-50 mg SALOFALK/kg/day in one single or 2-3 divided doses.

For long term treatment of ulcerative colitis, give your child 15-30 mg SALOFALK/kg/day in one single or 2 divided doses.

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

How to take it

Tear open the sachet along the end with the triangular mark.



Pour contents of sachet onto tongue.



Swallow the SALOFALK granules whole without chewing or crushing.



Drink some water to wash down the granules.

When to take it

Take SALOFALK the same time each day. This will help you remember when to take SALOFALK.

How long to take it

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

If you forget to take SALOFALK

If you forget to take a dose of 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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take 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 taken too much SALOFALK granules. Do this 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.

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 take SALOFALK.

Do not stop taking 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 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.

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
- 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 taking SALOFALK

Storage

- Keep your SALOFALK 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 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 taking SALOFALK or the expiry date has passed, 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.

Ingredients

Each SALOFALK sachet contains either 500 mg, 1 g or 1.5 g of the active ingredient, mesalazine.

Each SALOFALK sachet also contains the following inactive ingredients:

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

SALOFALK 500 mg granules are available in packs of 100 sachets.

SALOFALK 1 g granules are available in packs of 100 sachets.

SALOFALK 1.5 g granules are available in packs of 60 sachets.

Manufacturer/Supplier

SALOFALK granules 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

This leaflet was prepared in March 2010.

Australian Registration Number:

SALOFALK granules 500 mg sachet
AUST R 80648
SALOFALK granules 1 g sachet
AUST R 80649
SALOFALK granules 1.5 sachet
AUST R 143611

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