

SALOFALK® enteric coated tablets

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.

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

Ask your doctor or pharmacist if you have any concerns about taking SALOFALK.

Keep this leaflet with the medicine.

You may want to read it again.

What SALOFALK is used for

SALOFALK tablets contain the active 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) and Crohn's ileitis and colitis (inflammation of the large bowel and last section of the small bowel).

Ask your doctor if you have any questions about why SALOFALK tablets 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 take it

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.

Children over 6 years old

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

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 :

- **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 taking 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.**

SALOFALK 500 mg tablets contain 49 mg sodium per tablet. The maximum daily dose of this product is 441 mg per day. This should be particularly taken into account for those on a low salt diet.

If you have not told your doctor about any of the above, tell them before you start to take 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
- 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 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 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 Crohn's ileitis and colitis take 3 g to 4.5 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. For Crohn's ileitis and colitis take 1.5 g to 3 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 will tell you how much SALOFALK your child should take.

For acute ulcerative colitis, the usual dose for a child is 30-50 mg SALOFALK/kg/day in one single or 2-3 divided doses.

For long term treatment of ulcerative colitis, the usual dose for a child is 15-30 mg SALOFALK/kg/day in one single or 2 divided doses.

How to take it

Swallow the tablets whole with a glass of water.

DO NOT CHEW OR CRUSH.

When to take it

The tablets should be taken at least one hour before a meal.

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 it

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 take 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 taken too much SALOFALK tablets. Do this even if there are no signs of discomfort or poisoning.

Possible symptoms of overdose may include feeling sick, vomiting and diarrhoea.

While you are taking it

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.

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
- 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.

Stop taking SALOFALK and contact your doctor 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 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 taking it

Storage

Keep SALOFALK in their original package until it is time to take them.

If you take them out of their packaging, they may not keep as well.

Keep SALOFALK in a cool dry place, protected from light 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 tablets that are left over.

Product description

What it looks like

SALOFALK are butter yellow to ochre, oblong, enteric-coated tablets, lustreless with a smooth surface and no perceptible cracking.

Ingredients

Each SALOFALK enteric-coated tablet contains 500 mg or 1 g of the active ingredient, mesalazine. The 500 mg tablets are available in packs of 100. The 1 g tablets are available in starter packs of 10 or packs of 60 tablets.

It also contains the following inactive ingredients:

- anhydrous sodium carbonate (500 mg tablet only)
- glycine (500 mg tablet only)
- povidone
- microcrystalline cellulose
- croscarmellose sodium
- colloidal anhydrous silica
- calcium stearate
- hypromellose
- methacrylic acid copolymer
- purified talc
- titanium dioxide
- iron oxide yellow
- macrogol 6000
- eudragit E100 (500 mg tablet only).

Sponsor

Dr Falk Pharma Australia Pty Ltd,
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Australian Registration Numbers:

500 mg - AUST R 133472

1 g - AUST R 285903

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