

Package leaflet: Information for the user
Salofalk 500mg gastro-resistant tablets
Mesalazine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Salofalk 500mg tablets are and what they are used for
2. What you need to know before you take Salofalk 500mg tablets
3. How to take Salofalk 500mg tablets
4. Possible side effects
5. How to store Salofalk 500mg tablets
6. Contents of the pack and other information

1. What Salofalk 500mg tablets are and what they are used for

Salofalk 500mg tablets contain the active substance mesalazine, an anti-inflammatory agent used to treat inflammatory bowel disease.

Salofalk 500mg tablets are used for

- the treatment of acute episodes and prevention of further episodes (recurrence) of an inflammatory disease of the large intestine (colon), known by doctors as ulcerative colitis.

2. What you need to know before you take Salofalk 500mg tablets

Do not take Salofalk 500mg tablets

- If you are allergic to mesalazine, to salicylic acid, to salicylates such as Aspirin® or to any of the other ingredients of this medicine (listed in section 6).
- If you have a serious liver or kidney disease.

Warnings and precautions

Talk to your doctor before taking Salofalk 500mg tablets

- If you have a history of problems with your lungs, particularly if you suffer from **bronchial asthma**.
- If you have a history of allergy to sulphasalazine, a substance related to mesalazine.
- If you suffer with problems of your **liver**.
- If you suffer with problems of your **kidney**.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Further precautions

During treatment your doctor may want to keep you under close medical supervision, and you may need to have regular blood and urine tests.

In rare cases, in patients who have undergone bowel resection/bowel surgery in the ileocecal area with removal of the ileocecal valve, it has been observed that Salofalk 500mg tablets are excreted undissolved in the stool, due to an excessively rapid passage through the bowel. If you notice this occurrence in your own case, please inform your doctor.

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.

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 section 4.

Other medicines and Salofalk 500mg tablets

Tell your doctor if you take or use any of the medicines mentioned below, as the effects of these medicines may change (interactions):

- **Azathioprine, 6-mercaptopurine or thioguanine** (medicines used to treat immune disorders).
- **Certain agents that inhibit blood clotting** (medicines for thrombosis or to thin your blood, e.g. warfarin)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. It may still be all right for you to use Salofalk 500mg tablets and your doctor will be able to decide, what is suitable for you.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should only use Salofalk 500mg tablets during pregnancy, if your doctor tells you to.

You should also only use Salofalk 500mg tablets during breast-feeding, if your doctor tells you to, as this medicine may pass into breast milk.

Driving and using machines

Salofalk 500mg tablets have no or negligible influence on the ability to drive or use machines.

Salofalk 500mg tablets contain sodium

This medicinal product contains 49 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 2.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Salofalk 500mg tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration

Salofalk 500mg tablets are for oral use only.

Take the tablets in the morning, at midday and in the evening, 1 hour before meals. They should be swallowed whole, not chewed, and taken with plenty of fluid.

Dosage

Adults and the elderly

	Ulcerative colitis	
	acute episode	prevention of recurrence/long-term treatment
Mesalazine (active substance)	1.5 g–3.0 g	1.5 g
Salofalk 500mg gastro-resistant tablets	3 x 1 to 3 x 2	3 x 1

Use in children

There is only limited documentation for an effect in children (age 6-18 years).

Children 6 years of age and older

Please ask your doctor about the precise dosage of Salofalk 500mg tablets for your child.

In acute episodes

to be determined individually, starting with 30-50 mg mesalazine per kg body weight per day that should be given in divided doses. The maximum dose is 75 mg mesalazine per kg body weight per day. The total dose should not exceed the maximum adult dose.

To prevent a relapse

to be determined individually, starting with 15-30 mg mesalazine per kg body weight per day that should be given in divided doses. The total dose should not exceed the recommended adult dose.

It is generally recommended that half the adult dose should be given to children up to a body weight of 40 kg; and the normal adult dose to those above 40 kg.

Duration of treatment

How long you will use the medicine depends upon your condition. Your doctor will decide how long you are to continue the medication.

You should follow the treatment with Salofalk 500mg tablets regularly and consistently both during the acute episode of inflammation and also as long-term treatment, because this is the only way to achieve the desired therapeutic effect.

If you think that the effect of Salofalk 500mg tablets is too strong or too weak, talk to your doctor.

If you take more Salofalk 500mg tablets than you should

Contact a doctor if you are in doubt, so he or she can decide what to do.

If you use too much Salofalk 500mg tablets on one occasion, just take your next dose as prescribed. Do not use a smaller amount.

If you forget to take Salofalk 500mg tablets

Do not take a larger than normal dose of Salofalk 500mg tablets next time, but continue treatment at the prescribed dosage.

If you stop taking Salofalk 500mg tablets

Do not stop taking this product until you have talked to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are very rare. If you get any of the following symptoms after taking this medicine, you should contact your doctor immediately

- **Allergic skin rash**
- **Fever**
- **Breathing difficulties.**

If you experience a marked reduction of your general health, especially if accompanied by fever, and/or a sore throat and mouth, stop using these tablets and contact your doctor immediately. These symptoms can, very rarely, be due to a fall in the number of white cells in your blood (a condition called agranulocytosis) which may make you more prone to developing a serious infection. A blood test can confirm whether your symptoms are due to an effect of this medicine on your blood.

Stop using mesalazine and seek medical attention immediately if you notice any of the following symptoms:

- 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.

The following side effects have also been reported by patients using mesalazine:

Common side effects (may affect up to 1 in 10 people)

- Headache

Uncommon side effects (may affect up to 1 in 100 people)

- Abdominal pain, diarrhoea, dyspepsia, wind (flatulence), nausea and vomiting
- Severe abdominal pain because of acute inflammation of the pancreas
- Changes in liver function parameters, changes in pancreatic enzymes
- Changes in the number of white blood cells

Rare side effects (may affect less than 1 in 1,000 patients)

- Dizziness
- Chest pain, breathlessness or swollen limbs because of an effect on your heart
- Jaundice or abdominal pain because of liver and bile flow disorders
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)
- Joint pain
- Feeling weak or tired

Very rare side effects (may affect less than 1 in 10,000 patients)

- Fever, sore throat or malaise, due to blood count changes
- Skin rash or inflammation, allergic condition which causes joint pain, skin rashes and fever
- Severe diarrhoea and abdominal pain because of an allergic reaction to this medicine within the bowel
- Numbness and tingling in the hands and feet (peripheral neuropathy)

- Shortness of breath, cough, wheezing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions
- Hair loss and the development of baldness
- Muscle pain
- Changes in kidney function, sometimes with swollen limbs or flank pain
- Reversible decrease in semen production

Not known (frequency cannot be estimated from the available data)

- Kidney stones and associated kidney pain (see also section 2)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly as follows:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Salofalk 500mg tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

6. Contents of the pack and other information

What Salofalk 500mg tablets contain

The active substance is mesalazine. One tablet of Salofalk 500mg tablets contains 500 mg mesalazine.

The other ingredients are Calcium stearate; cellulose, microcrystalline; croscarmellose sodium; basic butylated methylacrylate copolymer (=Eudragit E); methacrylic acid-methyl methacrylate copolymer (1:1) (=Eudragit L); glycine; silica, colloidal anhydrous; hypromellose; macrogol 6000; sodium carbonate, anhydrous; povidone K25; talc; colouring agents: titanium dioxide (E 171); iron oxide hydrate (E 172)

What Salofalk 500mg tablets look like and contents of the pack

Salofalk 500mg tablets are oval, light yellow to ochre, gastro-resistant tablets, matt with smooth surface; they are not scored.

Salofalk 500mg tablets are available in blister packs of 20, 45, 50, 90, 100 and 300 tablets.

Not all package sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom: Salofalk.

Germany: Falk-Asa.

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