

Package leaflet: Information for the user

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

1. What Salofalk 1g tablets are and what they are used for

Salofalk 1g tablets contain the active substance mesalazine, an anti-inflammatory agent used to treat inflammatory bowel disease.

Salofalk 1g tablets are used for the treatment of acute episodes of mild to moderate forms of an inflammatory disease of the large intestine (colon), called ulcerative colitis.

2. What you need to know before you take Salofalk 1g tablets

Do not take Salofalk 1g tablets:

- If you are allergic to mesalazine, salicylic acid, salicylates such as acetylsalicylic acid (e.g., 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 or pharmacist before taking Salofalk 1g 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, which is a substance related to mesalazine**.
 - If you have **liver** problems.
 - If you have **kidney** problems.
 - If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Mesalazine may produce red-brown urine discoloration after contact with sodium hypochlorite bleach in the toilet water. It concerns a chemical reaction between mesalazine and bleach and is harmless.

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 patients who have undergone certain types of bowel surgery, Salofalk 1g tablets may be excreted undissolved in the stool. If you notice this, 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 drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) 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 1g tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Salofalk 1g tablets can affect the way some other medicines work. Also, some other medicines can affect the way Salofalk 1g tablets work.

In particular, tell your doctor or pharmacist if you are taking:

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

You may still be able to use Salofalk 1g tablets and your doctor will 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 1g tablets during pregnancy if instructed by your doctor.

You should only use Salofalk 1g tablets during breast-feeding if instructed by your doctor, as this medicine may pass into breast milk.

Driving and using machines

Salofalk 1g tablets have no influence on your ability to drive and use machines.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Salofalk 1g tablets

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

Dosage

Take one Salofalk 1g tablet three times a day (morning, midday and evening), or as instructed by your doctor.

Method of administration

Salofalk 1g tablets are for oral use only.

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

Use in children

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

Children 6 years of age and older

Ask your doctor about the precise dosage of Salofalk 1g tablets for your child. The dosage depends on how severe the condition is and on your child's body weight.

The dose should 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.

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.

Due to the size of Salofalk 1g tablets and the dosage recommendations, preparations of lower strengths should be used in children (e.g., Salofalk 500mg gastro-resistant tablets or Salofalk 500mg gastro-resistant prolonged-release granules).

Duration of treatment

The treatment of acute episodes of ulcerative colitis usually lasts 8 weeks. The length of treatment will depend upon your condition. Your doctor will decide how long you are to continue the medication.

You should take Salofalk 1g tablets regularly and consistently during the acute episode of inflammation so the desired therapeutic effect can be achieved.

If you think that the effect of Salofalk 1g tablets is too strong or too weak, talk to your doctor.

If you take more Salofalk 1g tablets than you should

Contact your doctor if you are in doubt as they can decide what to do. If you take too many Salofalk 1g tablets on one occasion, take your next dose as prescribed. Do not use a smaller amount.

If you forget to take Salofalk 1g tablets

If you miss a dose, continue your treatment at the prescribed dosage. Do not take a double dose to make up for the forgotten one.

If you stop taking Salofalk 1g tablets

Do not stop taking this product before having spoken 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.

If you get any of the following symptoms after taking this medicine, you should contact your doctor and stop the intake of Salofalk 1g tablets immediately:

- **General allergic reactions** such as skin rash, fever, joint pain and/or breathing difficulties or a general inflammation of your large bowel (causing severe diarrhoea and abdominal pain). These reactions are very rare.
- A marked reduction of your general health, especially if accompanied by fever, and/or a sore throat and mouth. These symptoms can, very rarely, be due to a fall in the number of white cells in your blood, which may make you more prone to developing a serious infection (**agranulocytosis**). Other cells of the blood may also be affected (e.g., platelets or red cells causing **aplastic anaemia or thrombocytopenia**) and cause symptoms which may include unexplained bleeding, purple spots or patches under your skin, anaemia (feeling tired, weak and looking pale, especially on lips and nails). A blood test can confirm whether your symptoms are due to an effect of this medicine on your blood. These reactions are very rare.
- **Serious skin rashes** with 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, widespread rash, fever and enlarged lymph nodes. These can be preceded by fever and flu-like symptoms. These reactions occur in an unknown number of patients (frequency not known).
- Shortness of breath, chest pain or irregular heartbeat, or swollen limbs which may be indicative of **cardiac hypersensitivity reactions**. These reactions are rare.
- **Problems with your kidney function** (can occur very rarely), e.g., a change in the colour or amount of urine produced and swollen limbs or a sudden flank pain (caused by a kidney stone) (occur in an unknown number of patients (frequency not known)).

The following side effects have also been reported by patients using medicines containing mesalazine, the active substance in Salofalk 1g tablets:

- Common side effects** (may affect up to 1 in 10 people)
- Headache
 - Rash, itching

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

Rare side effects (may affect up to 1 in 1,000 people)

- Dizziness
- 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 up to 1 in 10,000 people)

- Shortness of breath, cough, wheezing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions
- Muscle pain
- Hair loss and the development of baldness
- Numbness and tingling in the hands and feet (peripheral neuropathy)
- Reversible decrease in semen production

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 via the 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 1g 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 blister and the carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Salofalk 1g tablets contain

The active substance is mesalazine. Each Salofalk 1g tablet contains 1g of mesalazine.

The other ingredients are:

Microcrystalline cellulose, povidone K 25, croscarmellose sodium, methacrylic acid methyl methacrylate copolymer (1:1) (Eudragit L 100), methacrylic acid methyl methacrylate copolymer (1:2) (Eudragit S 100), calcium stearate [herbal origin], talc, Macrogol 6000, hypromellose, colloidal anhydrous silica, iron oxide yellow (E172), titanium dioxide (E171).

What Salofalk 1g tablets look like and contents of the pack

Salofalk 1g tablets are yellow to ochre yellow, oblong, biconvex, rounded edges gastro-resistant tablets with a smooth surface.

Salofalk 1g tablets are available in packs of 20, 50, 60, 90, 100 and 150 gastro-resistant tablets.

Not all pack 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:

Cyprus, Germany, Greece, Hungary and United Kingdom: Salofalk®

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