

Package leaflet: information for the user

Salofalk® 250mg Gastro-Resistant Tablets Mesalazine (5-aminosalicylic acid)

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.
- 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 250mg tablets are and what they are used for
2. What you need to know before you take Salofalk 250mg tablets
3. How to take Salofalk 250mg tablets
4. Possible side effects
5. How to store Salofalk 250mg tablets
6. Contents of the pack and other information

1. What Salofalk 250mg tablets are and what they are used for

Salofalk 250mg tablets contain the active substance mesalazine, an anti-inflammatory agent used to treat inflammatory bowel disease.

Salofalk 250mg tablets are used for the management of ulcerative colitis and treatment of Crohn's disease.

2. What you need to know before you take Salofalk 250mg tablets

Do not take Salofalk 250mg tablets:

- If you are allergic to mesalazine, salicylic acid, salicylates such as acetylsalicylic acid (e.g., aspirin) or 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 you start taking Salofalk 250mg 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.

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.

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.

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 250mg tablets

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

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

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 alright for you to use Salofalk 250mg 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 250mg tablets during pregnancy if your doctor tells you to.

You should only use Salofalk 250mg tablets during breast-feeding if your doctor tells you to as this medicine may pass into breast milk.

Driving and using machines

There are no effects on the ability to drive and use machines.

Salofalk 250mg tablets contain sodium

The maximum recommended daily dose of this medicinal product contains 576 mg sodium (found in table salt). This is equivalent to 29% of the adult recommended maximum daily dietary intake for sodium. Talk to your doctor or pharmacist if you need 8 or more Salofalk 250mg tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take Salofalk 250mg tablets

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

Dosage:

Adults and the elderly

Unless otherwise prescribed by your doctor, the recommended dose for the treatment of acute episodes of ulcerative colitis is: two tablets three times a day – morning, noon and evening with water and after meals. In severe cases your doctor may decide to double the dose.

For long term treatment the recommended dose is two tablets three times a day.

Method of administration:

Salofalk 250mg tablets are for oral use only.

Use in children and adolescents

There is little experience and information about the effect of this medicine when used in children aged 6-18 years.

Children 6 years of age and older

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

In acute episodes: To be determined individually, starting with 30-50mg mesalazine per kg body weight per day that should be given in divided doses. The maximum dose is 75mg 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 15-30mg 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 40kg and the normal adult dose to those above 40kg.

Duration of treatment

The treatment of acute episodes of ulcerative colitis usually lasts 8 weeks. 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 250mg tablets regularly and consistently, because this is the only way to achieve the desired therapeutic effect.

If you think that the effect of Salofalk 250mg tablets is too strong or too weak, talk to your doctor.

If you take more Salofalk 250mg tablets than you should

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

If you take too many Salofalk 250mg tablets on one occasion, just take your next dose as prescribed.

Do not use a smaller amount.

If you forget to take Salofalk 250mg tablets

Do not take a double dose to make up for a forgotten dose, continue treatment at the prescribed dosage.

If you stop taking Salofalk 250mg 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.

If you get any of the following symptoms after taking this medicine, you should contact your doctor and stop the intake of Salofalk 250mg 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 mesalazine:

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 1000 people)

- Dizziness
- Jaundice or abdominal pain because of liver or 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 10000 people)

- 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
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- 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 as follows:

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Salofalk 250mg tablets

- Keep this medicine out of the sight and reach of children.
- Do not use the tablets after the expiry date which is stated on the blister strips and carton. The expiry date refers to the last day of that month.
- Do not store above 25°C.

6. Contents of the pack and other information

What Salofalk 250mg tablets contain

The active substance is mesalazine and one tablet contains 250mg of mesalazine.

The other ingredients are:

Sodium carbonate (E500), glycine, povidone K25, microcrystalline cellulose, silica, colloidal anhydrous, calcium stearate, hypromellose, methacrylic acid methacrylate copolymer (1:1) (Ph.Eur.) (rel. molar mass: approx. 135000) (Eudragit L), talc, titanium dioxide (E171), hydrated iron(III) oxide (E172), basic butylated methacrylate copolymer (Ph.Eur.) (rel. molar mass: approx. 150000) (Eudragit E), macrogol 6000.

What Salofalk 250mg tablets look like and contents of the pack

Round, biconvex, yellow gastro-resistant tablets.

Each box of Salofalk 250mg tablets contains 100 or 300 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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