

Package leaflet: Information for the user

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

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

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

Salofalk 500mg granules are used for:

- the treatment of acute episodes and prevention of further episodes (recurrence) of mild to moderate ulcerative colitis, an inflammatory disease of the large intestine (colon).

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

Do not take Salofalk granules

- 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 before taking Salofalk 500mg granules

- 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.

If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears contact your doctor immediately.

Other medicines and Salofalk granules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular:

- **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)
- **Lactulose** (medicine used to treat constipation) or **other preparations that can change the acidity of your stools**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. It may still be all right for you to use Salofalk granules 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 granules during pregnancy if your doctor tells you to.

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

Driving and using machines

Salofalk granules have no or negligible influence on the ability to drive or use machines.

Salofalk 500mg granules contain aspartame, sucrose and sodium

This medicine contains 1 mg aspartame in each sachet of Salofalk 500mg granules. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take Salofalk 500mg granules

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

Method of administration

Salofalk granules are for oral use only.

Salofalk granules should **not be chewed**. You should take the Salofalk granules by placing the granules directly on the tongue and then swallowing them with plenty of liquid without chewing.

Dosage

Age and body weight	Single dose	Total daily dose
Adults, elderly and children weighing more than 40 kg		
Treatment of acute episodes	1 to 6 sachets Salofalk 500mg granules	1 x 3-6 sachets or 3 x 1-2 sachets
Prevention of further episodes	1 to 6 sachets Salofalk 500mg granules	3 x 1 sachet or 1 x 6 sachets (for patients at increased risk for recurrence)
Children 6 years of age and older		
Treatment of acute episodes		30-50 mg mesalazine/kg body weight/day once daily or in divided doses
Prevention of further episodes		15-30 mg mesalazine/kg body weight/day in divided doses

Adults and the elderly

Unless otherwise prescribed by your doctor, the normal dosage for the **treatment of acute episodes of ulcerative colitis** is:

Depending on the clinical requirements in the individual case, 3 to 6 sachets of Salofalk 500mg granules (equivalent to 1.5 to 3 g mesalazine per day) once daily preferably in the morning or 1 to 2 sachets three times daily (in the morning, at midday, in the evening).

To prevent a relapse of ulcerative colitis

The normal dosage to prevent further episodes of ulcerative colitis is:

1 sachet of Salofalk 500mg granules three times daily (equivalent to 1.5 g mesalazine per day).

If upon the decision of your doctor you are at increased risk for recurrence, the dosage for prevention of further episodes of ulcerative colitis is:

6 sachets of Salofalk 500mg granules once daily preferably in the morning (equivalent to 3 g mesalazine per day).

In general, for dose recommendations greater than 1.5 g mesalazine and up to 3 g mesalazine, Salofalk

1000mg, Salofalk 1.5g or Salofalk 3g granules should be used if possible.

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 granules 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 once daily preferably in the morning or 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

The treatment of acute episodes of ulcerative colitis usually lasts 8 weeks. Your doctor will decide how long you need to continue the treatment with this medicine. This will depend on your condition.

To obtain the maximum benefit from this medicine, you should use Salofalk granules regularly and consistently both during the acute episode of inflammation and also as long-term treatment as directed.

If you think that your Salofalk granules are too strong or too weak, talk to your doctor.

If you take more Salofalk granules 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 granules on one occasion, just take your next dose as prescribed. Do not use a smaller amount.

If you forget to take Salofalk granules

Do not take a double dose to make up for a forgotten dose.

If you stop taking Salofalk granules

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

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

4. Possible side effects

Like all medicines, Salofalk granules can cause side effects, although not everybody gets them.

If you experience any of the following symptoms after taking this medicine, you should contact your doctor and stop the intake of Salofalk granules 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)).
- **Strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears**. These could be symptoms of increased pressure within your skull (idiopathic intracranial hypertension) (frequency not known [cannot be estimated from the available data]).

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 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)

- 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
- 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

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

5. How to store Salofalk 500mg granules

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

Do not use Salofalk granules after the expiry date which is stated on the carton and the sachet after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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

6. Contents of the pack and other information

What Salofalk 500mg granules contain

The active substance is mesalazine and one sachet of Salofalk 500mg granules contains 500 mg mesalazine.

The other ingredients are aspartame (E 951); carmellose sodium; cellulose, microcrystalline; citric acid; silica, colloidal anhydrous; hypromellose; magnesium stearate; methacrylic acid-methyl methacrylate copolymer (1:1) (Eudragit L 100); methylcellulose; polyacrylate dispersion 40 % (Eudragit NE 40 D containing 2 % nonoxynol 100); povidone K 25; simeticone; sorbic acid; talc; triethyl citrate; vanilla custard flavour (containing sucrose).

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

Salofalk 500mg prolonged-release granules are stick-formed or round, beige or brownish granules, with or without yellowish surface parts.

Each sachet contains 913 mg granules.

Salofalk 500mg granules are available in packs of 50, 100 and 300 sachets.

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:

Czech Republic, Denmark, Finland, Germany, Greece, Hungary, Ireland, Italy, Latvia, The Netherlands, Norway, Portugal, Slovakia, Slovenia, Sweden, Spain, United Kingdom: Salofalk.

Belgium, Luxembourg: Colitofalk.

Austria: Mesagran.

France: Osperzo.

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