Salofalk® gastro-resistant prolonged-release granules

Mesalazine 500mg / 1000mg / 1.5g / 3g

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What Salofalk granules are used for

Salofalk 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).

How Salofalk granules work

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

Before you use Salofalk granules

- *When you must not use them*

- if you are or have been told you are allergic (hypersensitive) to mesalazine, salicylic acid, salicylates such as acetylsalicylic acid (e.g. Aspirin) or any of the other ingredients of this medicine.
- if you have a serious liver and/or kidney disease.

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 using this medicine

You should only use Salofalk granules during pregnancy if your doctor tells you to.

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

- *Before you start use them*

Before you start taking this medicine, you should tell your doctor

- 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, where you will 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, 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 ”Side effects”.

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

- *Taking other medicines*

Please 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)
- **lactulose** (substance used for treating constipation) or **other preparations that can change the acidity of your stools**

Please tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use 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.

This medicine contains 1.0/ 2.0/ 3.0/6.0 mg aspartame per sachet. 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’.

How to use Salofalk granules

- *How much to use*

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

Adults and the elderly

Unless otherwise prescribed by your doctor, the normal dose for the *treatment of acute episodes of ulcerative colitis* is (per day)

- 3 sachets of Salofalk 500mg granules

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or
- 3 sachets of Salofalk 1000mg granules or
- 1-2 sachets of Salofalk 1.5g granules or
- 1 sachet of Salofalk 3g granules

The dose depends on the individual clinical requirement.

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
- 2 sachets of Salofalk 1.5g granules or 1 sachet of Salofalk® 3g granules once daily preferably in the morning (equivalent to 3 g mesalazine per day).

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.

In maintenance treatment: to be determined individually, starting with 15-30 mg/kg mesalazine per kg body weight per day that should be given in divided doses.

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 their high content in active substance, Salofalk 1.5g and 3g granules are therefore not suitable for children weighing less than 40 kg. Please use Salofalk 500mg granules or Salofalk 1000mg granules instead.

- *When to use them*

The daily dose should be taken preferably in the morning. It is also possible to take the prescribed daily dose in three divided doses (morning, afternoon and evening).

- *How to use them*

Use as directed by your doctor or pharmacist.
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.

- *How long to use it*

Use as directed by your doctor or pharmacist.
How long you will use the medicine depends upon your condition. The treatment of acute episodes of ulcerative colitis usually lasts 8 weeks. Your doctor will decide how long you are to continue the medication.

You should follow the treatment with Salofalk granules 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 granules is too strong or too weak, talk to your doctor.

- *If you forget to use it*

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

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.

This product is not interchangeable with other brand or dosage form of products containing mesalazine.

While you are using Salofalk granules
- *Things you must do*
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Salofalk granules.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*
- 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.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

- *Things to be careful of*

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

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,

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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-containing medicines:

Common side effects

- Headache
- Rash, itching

Uncommon side effects

- 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

- Dizziness
- Jaundice or abdominal pain because of liver and bile flow disorders
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity: itchy eruption and exaggerated sunburn on patches of sun-exposed skin)
- Kidney stones and associated pain
- Joint pain
- Feeling weak or tired

Very rare side effects

- 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Salofalk granules

- *Storage*

Keep out of the reach and sight of children.

Store below 30 °C.

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

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Salofalk granules are stick-formed or round, greyish white granules.

- *Ingredients*
- Active ingredient

Mesalazine

- Inactive ingredients

Aspartame (E 951); carmellose sodium; cellulose, microcrystalline; citric acid, anhydrous; silica, colloidal anhydrous; hypromellose; magnesium stearate; methacrylic acid-methyl methacrylate copolymer (1:1) (Eudragit L 100); methylcellulose; polyacrylate dispersion 40 per cent (Eudragit NE 40 D containing 2 per cent nonoxynol 100); povidone K 25; simeticone; sorbic acid; talc; titanium dioxide (E 171); triethyl citrate; vanilla custard flavor (containing sucrose), Ethanol (only present as residue in the final product, up to 1.25%).

- *MAL numbers*

MAL18081002ACRZ: Salofalk 500mg gastro-resistant prolonged-release granules

MAL18081004ACRZ: Salofalk 1000mg gastro-resistant prolonged-release granules

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MAL18081003ACRZ: Salofalk 1.5g gastro-resistant prolonged-release granules

MAL18081005ACRZ: Salofalk 3g gastro-resistant prolonged-release granules

Manufacturer
Losan Pharma GmbH
Otto-Hahn-Straße 13
79395 Neuenburg, Germany

For DR. FALK PHARMA GmbH, Germany

Product Registration Holder
DCH Auriga (Malaysia) Sdn Bhd (719V)
Lot 6, Persiaran Perusahaan, Seksyen 23, 40300 Shah Alam, Selangor Darul Ehsan, Malaysia

Date of revision
27/05/2026

Serial Number
NPRA(R2/2)251007/01555