SALOFALK® GASTRO-RESISTANT TABLETS

Mesalazine 500 mg

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What Salofalk tablets are used for

Salofalk tablets are used for

- the treatment of acute episodes and prevention of further episodes of an inflammatory disease of the large intestine (colon and rectum) known by doctors as ulcerative colitis.
- the treatment of acute episodes of Crohn's disease (an inflammatory bowel disease).

How Salofalk tablets work

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

Before you use Salofalk tablets

- *When you must not use it*

- if you are or have been told you are allergic (hypersensitive) to mesalazine, salicylic acid, to salicylates such as acetylsalicylic acid (e.g. Aspirin) or to any of the other ingredients of Salofalk tablets (these are listed in section "Product description").
- if you have a serious liver and/or kidney disease.

Pregnancy and lactation

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 tablets during pregnancy if your doctor tells you to.

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

- *Before you start to use it*

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

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 "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*

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 to thin your blood, e.g. warfarin)

Tell your doctor if you are using, have recently used or might use any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Driving and using machines

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

Salofalk 500mg tablets contain sodium

One Salofalk 500mg tablet contains 49 mg sodium (found in table salt). The maximum recommended daily dose of this medicinal product contains 441 mg sodium. This is equivalent to 22 % of the adult recommended maximum daily dietary intake for sodium. Talk to your doctor or pharmacist if you need 7 or more tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

How to use Salofalk tablets

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

Salofalk tablets are for oral use only.

- *How much to use*

The recommended dose is:

Adults and the elderly

Unless otherwise prescribed by your doctor, the normal daily doses of mesalazine (the active substance of Salofalk) or Salofalk tablets are:

	Crohn's disease	**Ulcerative colitis**	
	Acute episode	Acute episode	Prevention of recurrence/ long-term treatment

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Mesalazine (active substance)	1.5 g - 4.5 g	1.5 g - 3.0 g	1.5 g
Salofalk 500mg tablets	3 x 1 to 3 x 3	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 tablets for your child. The dosage depends on how serious the health condition is and on your child's body weight.

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

To prevent a relapse (ulcerative colitis): 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.

- When to use it
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.

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.

- *How long to use it*
Use as directed by your doctor or pharmacist.
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 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 tablets is too strong or too weak, talk to your doctor.

- *If you forget to use it*
Do not take a larger than normal dose of Salofalk tablets next time, but continue treatment at the prescribed dosage.

- *If you use too much (overdose)*
Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you are in doubt.
If you use too much Salofalk tablets on one occasion, just take your next dose as prescribed. Do not use a smaller amount.

While you are using Salofalk tablets
- *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.

- *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.

- *Things to be careful of*
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 people who have undergone bowel resection/bowel surgery in the ileocoecal area (in between small and large intestine) with removal of the ileocoecal valve, it has been observed that Salofalk tablets are passed out 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.

Side effects
Like all medicines, Salofalk tablets 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 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

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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 medicines containing mesalazine:

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

Uncommon: (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: (may affect less than 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: (may affect less than 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

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

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 may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Salofalk tablets
- *Storage*
Keep this medicine out of the sight and reach of children.

Store below 30 °C.

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.

- *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 500mg tablets are butter-yellow to ochre, oblong formed, gastro-resistant tablets, lustreless with smooth surface, no cracking perceptible.
Salofalk 500mg tablets are available in blister packs of 100 gastro-resistant tablets.

- *Ingredients*
Active ingredient
The active substance in Salofalk tablets is mesalazine. One Salofalk 500mg tablet contains 500 mg mesalazine.

Inactive ingredients
Basic butylated methacrylate copolymer (rel. molar mass: approx. 150000 (e.g. Eudragit E)), calcium stearate, croscarmellose sodium, iron oxide yellow (E 172), glycine, silica colloidal anhydrous, hypromellose, macrogol 6000, methacrylic acid methyl methacrylate copolymer (1:1) (rel. molar mass: approx. 135000 (e.g. Eudragit L)), microcrystalline cellulose, sodium carbonate, povidone K25, talc.

- *MAL number*
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