

# SALOFALK GASTRO-RESISTANT TABLETS

Mesalazine (250mg, 500mg)

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## What Salofalk tablets are used for

Salofalk tablets are used for:

- the treatment of acute (sudden and short) episodes and prevention of further episodes (recurrence) of an inflammatory disease of the large intestine (colon and rectum) known 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

Do not take Salofalk 500mg tablets

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

### 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 **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**.

### Taking other medicines

Please tell your doctor if you 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)

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

### 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 tablets during pregnancy, if your doctor tells you to.

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

### Driving and using machines

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

Salofalk tablets contain sodium. One Salofalk tablet contains 2.1 mmol (48 mg) sodium. If you need to be on a controlled sodium salt diet, you should take this into consideration.

### 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	Prevention of recurrence/ long-term treatment
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.

Due to the size of Salofalk tablets and the dosage recommendations, **Salofalk 250mg**

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**gastro-resistant tablets** should preferably be used in children.

### 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

Your doctor will decide how long you are to continue the medication. How long you will use the medicine depends upon your health condition.

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 the desired medicine effect can be achieved.

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 a doctor if you are in doubt, so that the doctor can decide the next steps to be taken.

If you use too much Salofalk tablets on one occasion, just take your next dose as prescribed. Do not use a lower dose.

### **While you are using it**

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

### 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 ileocecal area (in between small and large intestine) with removal of the ileocecal 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, this medicine can cause side effects, although not everybody gets them.

**All medicines can cause allergic reactions although serious allergic reactions are very rare. If you get any of the following symptoms after taking this medicine, you should contact your doctor immediately:**

- **Allergic skin rash**
- **Fever**
- **Breathing difficulties**

If you experience a marked reduction of your general health, especially if accompanied by fever, and/or a sore throat and mouth, stop using these tablets and contact your doctor immediately.

These symptoms can, very rarely, be due to a fall in the number of white cells in your blood (a condition called agranulocytosis) which may make you more prone to developing a serious infection. A blood test can confirm whether your symptoms are due to an effect of this medicine on your blood.

The following side effects have also been reported by using mesalazine:

**Rare side effects** (that affect less than 1 in 1,000 people):

- Abdominal pain, diarrhoea, wind, nausea and vomiting
- Headache, dizziness

**Very Rare side effects** (that affect less than 1 in 10,000 people):

- Changes in kidney function, sometimes with swollen limbs or flank pain because of renal disorders
- Severe abdominal pain because of acute inflammation of the pancreas
- Muscle and joint pain
- Jaundice or abdominal pain because of liver and bile flow disorders
- Hair loss and the development of baldness
- Numbness and tingling in the hands and feet (peripheral neuropathy)
- Reversible decrease in semen production.

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: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

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**Storage and Disposal of Salofalk tablets**Storage

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 or container. The expiry date refers to the last day of that month.

Once opened, the container should be used up within 6 months.

Do not store above 25°C.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Medicines should not be disposed of via wastewater or household waste. This measure will help to protect the environment.

**Product Description**What it looks like

Salofalk 250mg tablets are round, light yellow to ochre, matte with a smooth surface, not scored.

Salofalk 500mg tablets are oblong, butter yellow to ochre, lustreless with a smooth surface.

Salofalk 250mg and 500mg tablets are available in blister packs of 100 gastro-resistant tablets.

**Ingredients****Active ingredient:**

The active substance in Salofalk<sup>®</sup> tablets is mesalazine, and one Salofalk<sup>®</sup> 250mg tablet contains 250mg mesalazine whereas one Salofalk<sup>®</sup> 500mg tablet contains 500mg mesalazine.

**Inactive ingredients:**

For Salofalk 250mg tablet:

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

For Salofalk 500mg tablet:

Basic butylated methacrylate copolymer ((rel. molar mass: approx. 150000)) (= Eudragit E), calcium stearate, croscarmellose sodium, glycine, hydrated iron (III) oxide (E 172), hypromellose, macrogol 6000, methacrylic acid-methyl methacrylate copolymer (1:1) ((rel. molar mass: approx. 135000)) (= Eudragit L), microcrystalline cellulose, povidone K25, silica colloidal anhydrous, sodium carbonate anhydrous, talc, titanium dioxide (E171).

MAL number(s):

Salofalk 250mg Tablets:  
MAL19987335ACS

MAL number(s):

Salofalk 500mg Tablets:  
MAL19987336ACS

**Manufacturer**

Losan Pharma GmbH  
Otto-Hahn-Str. 13, 79395 Neuenburg  
Germany

For:

Dr. Falk Pharma GmbH  
Leinenweberstr. 5  
79108 Freiburg  
Germany

**Product Registration Holder**

LF Asia (Malaysia) Sdn Bhd (719-V)  
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40300 Shah Alam,  
Selangor Darul Ehsan

**Date of Revision**

17/12/2015

**Serial Number**

BPFK(R4/1)030915/00296