

Package leaflet: Information for the user

Salofalk 500mg Suppositories
Mesalazine

Read all of this leaflet carefully before you start using 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 suppositories are and what they are used for
2. What you need to know before you use Salofalk suppositories
3. How to use Salofalk suppositories
4. Possible side effects
5. How to store Salofalk suppositories
6. Contents of the pack and other information

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

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

Salofalk suppositories are used for:

- the treatment of mild and moderate episodes of an inflammatory disease in the rectum (back passage) known by doctors as ulcerative colitis or ulcerative proctitis.

2. What you need to know before you use Salofalk suppositories 500mg

Do not use Salofalk suppositories

- If you are allergic to salicylic acid, to salicylates such as acetylsalicylic acid (e.g., aspirin) or to 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 using this medicine:

- 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.

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 suppositories 500mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.

Pregnancy, breast-feeding and fertility

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 suppositories during pregnancy if your doctor tells you to.

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

Driving and using machines

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

Salofalk suppositories 500mg contain cetyl alcohol

Cetyl alcohol may cause local skin reactions (e.g., contact dermatitis).

3. How to use Salofalk suppositories 500mg

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

Method of administration

This medicine may only be used rectally, so it has to be inserted through the anus. Do NOT take by mouth.

Dosage

Adults and elderly:

The recommended dose is one or two suppositories two to three times daily.

Use in children

There is little experience and only limited documentation for an effect in children.

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 suppositories regularly and consistently, as directed.

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

If you use more Salofalk suppositories than you should

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

If you use too many suppositories on one occasion, just use your next dose as prescribed. Do not use a smaller amount.

If you forget to use Salofalk suppositories

Do not use a larger than normal dose of Salofalk suppositories next time, but continue treatment at the prescribed dosage.

If you stop using Salofalk suppositories

Do not stop using 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, 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 using Salofalk 500mg Suppositories 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: may affect up to 1 in 10 patients

- Rash, itching

Rare side effects (that affect less than 1 in 1,000 patients)

- Abdominal pain, diarrhoea, wind (flatulence), nausea and vomiting, constipation
- Headache, dizziness
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)

Very rare side effects (that affect less than 1 in 10,000 patients)

- Changes in kidney function, sometimes with swollen limbs or flank pain
- Severe abdominal pain because of acute inflammation of the pancreas
- Shortness of breath, cough, wheezing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions
- Muscle and joint pain
- Jaundice or abdominal pain because of liver or 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

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 via the Yellow Card Scheme Website: <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store

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

5. How to store Salofalk suppositories 500mg

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 strip and on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original container in order to protect contents from light.

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 protect the environment.

6. Contents of the pack and other information

What Salofalk suppositories contain

The active substance is mesalazine and one suppository contains 500mg mesalazine.

The other ingredients are

Hard fat, docusate sodium, cetyl alcohol.

What Salofalk suppositories look like and contents of the pack

Salofalk suppositories are in white opaque PVC/PE strips of 5.

Available in packs of 10 or 30 suppositories.

Not all packs may be marketed.

Marketing Authorisation Holder

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Manufacturer

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