

Package leaflet: Information for the patient

Salaza, 500 mg, suppositories

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 or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Salaza is and what it is used for
2. What you need to know before you take Salaza
3. How to take Salaza
4. Possible side effects
5. How to store Salaza
6. Contents of the pack and other information

1. What Salaza is and what it is used for

Salaza contains the active substance mesalazine, which is an anti-inflammatory agent for the treatment of Ulcerative colitis.

Salaza is indicated for:

- Distal Ulcerative colitis, an inflammatory disease of the last part of the colon e.i. large bowel and rectum (back passage).
 - Treatment of mild or moderate acute exacerbations;
 - Maintenance of remission.

2. What you need to know before you take Salaza

Do not take Salaza:

- if you are allergic (hypersensitive) to mesalazine, salicylates (for example: aspirin) or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney or liver disease.
- if you have a medical condition that can make you prone to bleeding.

Warnings and precautions

Talk to your doctor or pharmacist before using Salaza:

- If you suffer problems with your liver or your kidney.
- If you have a history of problems with your lungs, especially if you suffer bronchial asthma.
- If you have a history of allergy to sulphasalazine (a medicine used to treat rheumatic or inflammatory diseases), a substance related to mesalazine. In case you feel any symptoms, such as spasms, abdominal pain, fever, headache or skin rash or itching during treatment, do not take more suppositories and talk to your doctor immediately.
- If you have an ulcer in your stomach or bowel intestine
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine

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.

During treatment your doctor may supervise you more often and may ask you for regular blood and urine tests.

Serious skin reactions including 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 4.

Other medicines and Salaza

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

Before starting treatment with Salaza, you should tell your doctor if you are taking any of the following medicines (as your doctor may need to adjust your dose):

- Substances that inhibit blood clotting (medicines for thrombosis or to thin the blood), for example warfarin, since mesalazine may reduce its effects.
- Medicines used to treat immune disorders such as azathioprine, 6-mercaptopurine or thioguanine, since mesalazine may increase its effects.
- Medicines such as non-steroidal anti-inflammatory drugs (NSAIDs) and azathioprine, since they may be toxic for your kidney.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before using this medicine.

You should only use Salaza during pregnancy or breast-feeding if your doctor tells you to.

Driving and using machines

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

3. How to take Salaza

Always use this medicine exactly as your doctor 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.

It is recommended go to the toilet and empty your bowel before using the suppository.

It is advisable to introduce the suppository while you are lying on the left side and to remain in this position for about 1 hour.

Suppositories should be introduced deeply into the anus and should be retained in the rectum for 1-3 hours to increase the efficacy.

Your doctor may adjust the dose, depending on your characteristics and on the characteristics of your disease. The recommended dose in adults is:

- Treatment of acute phase:). one suppository twice or thrice daily (1000-1500 mg);
- Maintenance of remission: one suppository once or twice daily (500-1000 mg).

Use in children and adolescents

There is limited information of the use of Salaza in children younger than 18 years.

If you take more Salaza than you should

If you use more Salaza than you should, contact your doctor, hospital or emergency care, to get an opinion of the risk and advice on the action to be taken. Take the suppositories pack with you.

If you forget to take Salaza

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

It is important to take Salaza suppositories every day, even when you do not have symptoms of ulcerative colitis. Continue the treatment as prescribed by your doctor.

If you stop taking Salaza

Do not stop the treatment without first talking with your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines may cause allergic reactions although serious allergic reactions are very rare. If you get any of these symptoms after using this medicine, stop taking these suppositories and contact your doctor immediately:

- allergic skin rash,
- fever,
- difficulty in breathing.

If you experience fever or irritation of the throat or mouth, stop using these suppositories and contact your doctor immediately. These symptoms may be due very rarely to a reduction in the number of white cells in the blood (a condition called agranulocytosis).

Stop using mesalazine and seek medical attention immediately if you notice any of the following symptoms:

-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. These serious skin rashes can be preceded by fever and flu-like symptoms.

The following side effects have also been reported in patients using mesalazine:

Rare side effects (may affect up to 1 in 1000 people):

- abdominal pain, diarrhoea, flatulence, nausea and vomiting;
- headache, dizziness;
- chest pain, shortness of breath or swollen limbs due to an effect on the heart;
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

Very rare side effects: (may affect up to 1 to 10.000 people):

- problems with kidney function, sometimes with swollen limbs or flank pain;
- severe abdominal pain because of acute inflammation of the pancreas;
- worsening of colitis symptoms;
- fever, sore throat or feeling sick due to changes in blood count;
- shortness of breath, cough, wheezing, spot in the lungs x-ray due to allergic and/or inflammatory conditions in the lungs;
- diarrhoea and severe abdominal pain due to an allergic reaction to medicine at the bowel level;
- skin rash or inflammation;
- muscle and joint pain;
- jaundice or abdominal pain, due to liver or bile flow disorders;
- hair loss and development of baldness;
- erythema multiforme
- numbness and tingling of the fingers and toes (peripheral neuropathy);
- reversible decrease in semen production.
- blood count disorders

Adverse effects of unknown frequency (can not be estimated from the available data):

- kidney stones and associated kidney pain (see also section 2).
- severe cutaneous adverse reactions: Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN)

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 Pharmacovigilance Department of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Aleje Jerozolimskie 181C, 02-222 Warsaw, tel: +48 22 49 21 301, fax: +48 22 49 21 309, website: <https://smz.ezdrowie.gov.pl>.

Adverse drug reactions may also be reported to Marketing Authorisation Holder.

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

5. How to store Salaza

Do not store above 30°C.

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

Do not use this medicine if you notice signs of deterioration.

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. Content of the pack and other information

What Salaza contains

- The active substance is mesalazine. Each suppository contains 500 mg of mesalazine.
- The other ingredients are:
Hard fat.

What Salaza looks like and contents of the pack

Torpedo-shaped suppositories with greyish-white to slightly violet-reddish color, in PVC/PE films shells.

This medicine is available in packs of 12, 24, 30, 60 or 100 suppositories.

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