

PACKAGE LEAFLET: INFORMATION FOR THE USER

MESALAZIN

250mg and 500mg Film-Coated Tablet

MESALAZINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 • 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 •

What is in this leaflet?

1. What MESALAZIN is and what it is used for
2. Before you take MESALAZIN
3. How to take MESALAZIN
4. Possible side effects
5. How to store MESALAZIN

1. WHAT MESALAZIN IS AND WHAT IS IT USED FOR

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

Mesalazin tablets are used for:

The treatment of acute episodes and prevention of further episodes (recurrence) of an inflammatory disease of the large intestine (colon), known by doctors as ulcerative colitis.

2. BEFORE YOU TAKE MESALAZIN

Do not take Mesalazin Tablets:

- If you are allergic to salicylic acid, to salicylates such as aspirin or to any of the other ingredients of Mesalazin Tablets.
- If you have a serious liver or kidney disease.

Warnings and precautions

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.

Further precautions

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 patients who have undergone bowel resection/bowel surgery in the ileo-coecal area with removal of the ileocecal valve, it has been observed that Mesalazin Tablets are excreted 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.

Other medicines and Mesalazin Tablets

Tell your doctor if you take or use any of the medicines mentioned below as the effects of these medicines may change (interactions):

- **Certain medicines that affect 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, including medicines obtained without a prescription. It may still be all right for you to use Mesalazin Tablets and your doctor will be able to decide what is suitable for you

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 taking this medicine.

You should only use Mesalazin Tablets during pregnancy if your doctor tells you to.

You should only use Mesalazin Tablets during breastfeeding if your doctor tells you to as this medicine may pass into breast milk.

Driving and using machines

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

3. HOW TO TAKE MESALAZIN

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

Method of administration

Mesalazin Tablets are for oral use only.

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.

The recommended dose is:

Use in children and adolescents: 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 Mesalazin Tablets for your child. **In acute episodes:** to be determined individually, starting with 30 – 50 mg mesalazine per kg body weight per day to be given in divided doses. The maximum dose is 75mg mesalazine per kg body weight per day. The total dose should not exceed the maximum adult dose. **To prevent a relapse:** to be determined individually, starting with 15-30 mg mesalazine per kg body weight per day to 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 40kg and the normal adult dose to those above 40kg.

The daily dose may be divided into three portions, taken in the morning, at noon and at night.

Duration of treatment

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 Mesalazin 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 Mesalazin Tablets is too strong or too weak, talk to your doctor.

If you take more Mesalazin Tablets than you should

Contact a doctor if you are in doubt, so he or she can decide what to do. If you use too much Mesalazin on one occasion, just take your next dose as prescribed. Do not use a smaller amount.

If you forget to take Mesalazin Tablets

Do not take a double dose of Mesalazin Tablets next time, but continue treatment at the prescribed dosage.

If you stop taking using Mesalazin Tablets

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.

4. POSSIBLE 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 patients using mesalazine:

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

- Abdominal pain, diarrhoea, wind (flatulence), nausea and vomiting
- Headache, dizziness
- Chest pain, breathlessness or swollen limbs because of an effect on your heart

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
- Fever, sore throat or malaise, because of blood count changes
- Shortness of breath, cough, wheezing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions
- Severe diarrhoea and abdominal pain because of an allergic reaction to this medicine within the bowel
- Skin rash or inflammation
- 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

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.

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

5. HOW TO STORE MESALAZIN

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

This medicinal product does not require any special storage conditions.

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.