

Patient Information leaflet

MELANEZ 500

Mesalazine Suppositories BP 500 mg

Read all of this leaflet carefully before you start using this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Melanez 500 is and what it is used for
2. Before you or your child takes Melanez 500
3. How to use Melanez 500 Suppositories
4. Possible side effects
5. How to store Melanez 500
6. Further information

1. What Melanez 500 is and what it is used for

Melanez 500 contains the active substance Mesalazine, an anti-inflammatory agent used to treat inflammatory bowel disease.

Melanez 500 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 Melanez 500 suppositories

Do not use Melanez 500 suppositories

- If you are allergic to salicylic acid, to salicylates such as 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.

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 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 Melanez 500 Suppositories

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 for thrombosis or to thin your blood, e.g., warfarin).

Tell your doctor or pharmacist, if you are taking, have recently taken or might take any other medicines. It may still be all right for you to use Melanez 500 Suppositories 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 using this medicine.

You should only use Melanez 500 mg Suppositories during pregnancy if your doctor tells you to.

You should also only use Melanez 500 mg Suppositories during breast-feeding if your doctor tells you to, as this medicine may pass into breast milk.

Driving and using machines

Melanez 500 Suppositories are not expected to affect your ability to drive or operate machines.

Important information about some of the ingredients of Melanez 500 Suppositories

The other ingredient in Melanez 500 Suppositories is not likely to cause side effects (see section 6. Contents of the pack and other information).

3. How to use Melanez 500 Suppositories

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.

Dosage

Adults and older people

The recommended dose is one Melanez 500 suppository once a day, at bedtime.

Use in children

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

Duration of treatment

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 Melanez 500 mg Suppositories regularly and consistently, as directed.

If you think your Melanez 500 mg Suppositories are too strong or too weak, talk to your doctor

If you use more Melanez 500 mg 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 much Melanez 500 mg Suppositories on one occasion, just take your next dose as prescribed. Do not use a smaller amount.

If you forget to use Melanez 500 mg Suppositories

If you forget to use this medicine, use it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Then use the next dose at its usual time. Do not use a double dose to make up for a forgotten dose.

If you stop using Melanez 500 mg 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 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 using 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 suppositories 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 (may affect up to 1 in 1,000 patients):

Abdominal pain, diarrhoea, wind (flatulence), nausea and vomiting, constipation

- Headache, dizziness
- Chest pain, breathlessness or swollen limbs because of an effect on your heart
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)

Very rare side effects (may affect up to 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 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

Not known (frequency cannot be estimated from the available data)

- Kidney stones and associated kidney pain (see also section 2)

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 national reporting system:

5. How to store Melanez 500

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.

Store below 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 to protect the environment.

6. FURTHER INFORMATION

What Melanez 500 contains

The active substance in Melanez 500 Suppositories is mesalazine and one suppository of Melanez 500 Suppositories contains 500 mg mesalazine.

What Melanez 500 looks like and contents of the pack

Off white to light brown opaque bullet shaped suppository.

2 Blister of 5 suppositories in PVC/PVdC/PE packed in Carton along with leaflet.

Marketing Authorisation Holder

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