

MELANEZ SUPPOSITORIES

Mesalazine (500mg & 1g)

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What Melanez Suppositories is used for

- **Melanez Suppositories 500mg:**
Melanez Suppositories 500mg are used for treatment of acute episodes of inflammatory disease at large intestine, rectum and anal canal.

- **Melanez Suppositories 1g**
Melanez Suppositories 1g is used to treat ulcerative proctitis (inflammation of the anus and rectum (back passage)).

How Melanez Suppositories works

Melanez Suppositories contain mesalazine which is an anti-inflammatory agent used for treating inflammatory bowel disease.

Before you use Melanez Suppositories

-When you must not take it

Do not take Melanez Suppositories if:

- You are hypersensitive (allergic) to mesalazine, salicylic acid, salicylates such as aspirin or to any of the other ingredients of this medicine.
- You have serious liver or kidney disease.

-Before you start use it

Before you start using Melanez Suppositories, please tell your doctor or pharmacist if you have any of the following:

- History of problems with your lungs, especially if you suffer from bronchial asthma.
- History of allergy to sulphasalazine, a substance related to mesalazine.
- Suffering with problems of your liver.
- Suffering with problems of your kidney.

- Developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Further precautions:

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 "Side effects".

-Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. You should only use Melanez Suppositories during pregnancy if your doctor tells you do.

You should only use Melanez Suppositories during breast-feeding if your doctor tells you to, as this medicine and its metabolites may pass into breast milk. If the infant develops diarrhoea, the breast-feeding should be discontinued.

-Taking other medicines

Please 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)

Please tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines, including medicines obtained without a prescription. It may still be all right for you to use Melanez Suppositories and your doctor will be able to decide what is suitable for you.

-Driving and using machines:

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

How to use Melanez Suppositories

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

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

-How much to use

The recommended dose is"

-Adults and elderly

- **Melanez Suppositories 500mg:**
For the treatment of acute symptoms of inflammation, insert one Melanez Suppositories 500mg into the anus three times daily (equivalent to 1500mg mesalazine daily).

For long-term treatment, Melanez Suppositories 500mg gastro-resistant tablets can be used.

- **Melanez Suppositories 1g:**
One Melanez Suppositories 1g one to two times daily inserted into the anus.

-Children and adolescents

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

-When to use it

- **Melanez Suppositories 500mg:**
When used three times daily, Melanez Suppositories 500 mg should be inserted into the rectum in the morning, at mid-day and at bedtime.

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-Melanez Suppositories 1g:

Always use Melanez Suppositories 1g exactly as your doctor has told you. If you are not sure, check with your doctor.

To obtain the maximum benefit from this medicine, you should use Melanez Suppositories regularly and consistently, as directed.

-How long to use it

Your doctor will decide how long you need to continue the treatment with this medicine. This will depend on your condition. Do not stop taking this product until you have talked to your doctor.

If you think Melanez Suppositories effect is too strong or too weak, talk to your doctor or pharmacist.

-If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until the time to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Contact a doctor if you are in doubt, so they 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.

While you are using it

-Things you must do

-Patient

You must clean the area around the rectum with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth. Lie on one side with knees bent up to the abdomen or lie on back with feet and legs held up.

-Doctor or any other individual

Detach the suppository by holding the strip upright and carefully peel the wrapper evenly down both sides. Moisten suppository if dry. Hold the suppository between index finger and thumb, locate the anus and gently insert suppository tip end first with index finger. The suppository must be fully inserted into rectum against the wall of rectum. Hold the buttocks

together lying down for about 5 minutes to avoid having the suppository comes out. Discard used materials and wash hands thoroughly.

Do not open suppository if it seems soft. Hold the foil wrapper under cold water or place it in refrigerator for few minutes to harden it before removing the wrapper.

Should Melanez Suppositories cause acute intolerance reactions such as abdominal cramps, acute abdominal pain, fever severe headache and rash, therapy should be discontinued immediately

-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 test.

Side effects

Like all medicines, Melanez Suppositories can cause side effects, although not everyone 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 Melanez 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.

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, widespread rash, fever and enlarged lymph nodes. These serious skin rashes can be preceded by fever and flu-like symptoms.

The following side effects have also been reported in patients using medicines containing mesalazine.

Rare:

- abdominal pain, diarrhoea, wind (flatulence), nausea and vomiting, constipation
- headache, dizziness
- chest pain, breathlessness or swollen limbs because of an effect on your heart
- photosensitivity: Itchy eruption and exaggerated sunburn or patches of sun exposed skin.

Very rare:

- 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:

- Kidney stones and associated kidney pain

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If any of the side effects gets serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Melanez Suppositories

-Storage

Store in a dry place, below 30°C. Protect from light. Keep medicine out of sight and reach of children.

Shelf life is 24 months. Do not use this medicine after the expiry date.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

- Melanez Suppositories 500mg

An off white to light brown opaque bullet shaped suppository (Length: 26.7 mm, Width: 8.5 ± 0.3 mm)

- Melanez Suppositories 1g

An off white to light brown opaque bullet shaped suppository (Length: 33.0 mm, Width: 10.4 ± 0.3 mm)

-Ingredients

-Active ingredient

Mesalazine.

-Inactive ingredient/Excipient

Hard Fat.

-MAL number

Melanez Suppositories 500mg:
MAL24086028AZ

Melanez Suppositories 1g:
MAL24086033AZ

Product Registration Holder & Manufacturer

-Product Registration Holder

Pharmaniaga Marketing Sdn Bhd
No 7, Lorong Keluli 1B, Kawasan
Perindustrian, Bukit Raja Selatan,
Seksyen 7, 40000 Shah Alam,
Selangor Darul Ehsan,
Malaysia.

-Manufacturer

Bliss GVS Pharma Ltd.
Plot No. 11, Dewan Udyog Nagar,
Aliyali, Palghar- 401 404, Maharashtra,
India

Date of revision

28/1/2025

Serial Number:

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