

PENTASA[®] SUPPOSITORIES

Mesalazine (1g)

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What PENTASA[®] is used for

PENTASA[®] is used to treat ulcerative proctitis (inflammation of the anus and rectum), disease associated with inflammation, ulcers and sores in the bowel.

How PENTASA[®] works

The name of this medicine is PENTASA[®] Suppositories 1g. Each suppository contains mesalazine 1g as the active ingredient. Mesalazine belongs to a group of medicines called salicylates.

Mesalazine is the active component of sulfasalazine, which has been used for many years in the treatment of ulcerative proctitis.

Before you use PENTASA[®]

-when you must not use it

DO NOT take PENTASA[®] if you:

- Are allergic to mesalazine, salicylic acid or its derivatives or to any of the other ingredients of PENTASA[®].
- Have severe liver and/or kidney impairment.

-Before you start to use it

Check with your doctor before taking PENTASA[®] if you

- pregnant or breastfeeding or planning to become pregnant.

Mesalazine is found in breast milk.

PENTASA[®] should be used with caution during pregnancy and lactation and only if the potential

benefits outweigh the possible hazards.

Take special care with PENTASA[®] if:
-You have impaired liver function

The medicine is not recommended for use in people with renal impairment. The kidney function should be checked regularly, especially during the early phase of treatment. Kidney toxicity that are caused by Mesalazine should be suspected in people who developing kidney dysfunction during treatment.

The frequency of Kidney function monitoring should be increased when mesalazine is use together with other known kidney toxicity inducing medicines.

Mesalazine-induced heart allergic reactions have been reported rarely. Serious blood disease have been reported very rarely with mesalazine. Blood test for differential blood count is recommended prior to and during treatment.

-Taking other medicines

Please tell you doctor or pharmacist if you are taking/using or have recently taken/used, any other medication, including medicines obtained without a prescription.

Combination therapy with PENTASA[®] and azathioprine, or 6-mercaptopurine or thioguanine (immunosuppressant agent that will affect your immune system) have in several studies shown a higher frequency of decrease bone marrow activity effects and an interaction seems to exist. However, the mechanism behind the interaction is not fully established. Regular monitoring of white blood cells is recommended and dosage regime of thiopurines should be adjusted or discontinued accordingly.

How to use PENTASA[®]

-How much to use

Always use PENTASA[®] exactly as your doctor has told you. You should check with your doctor if you are not sure.

Recommended dosage: 1 suppository 1-2 times daily.

-Instruction for use

1. A visit to the toilet is recommended before inserting a suppository.
2. Open the foil bag at the tear mark.
3. The suppository is inserted in the rectum until resistance is felt and disappeared again.
4. In order to facilitate the administration, the suppository can be moistured with water or moisture cream.
5. If the suppository is discharged within the first 10 minutes, another can be inserted.

-When to use it

Always use PENTASA[®] exactly as your doctor has told you. If you are not sure, check with your doctor

-How long to use it

You should continue to use PENTASA[®] for as long as your doctor tells you to.

-If you forget to use it

Use it as soon as you remember, unless it is nearly time for your next dose. Do not take a double dose to make up for the missed dose

-If you use too much (overdose)

If you take more PENTASA[®] than you should:
Seek treatment immediately.

While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking PENTASA[®].

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-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give PENTASA[®] to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

If PENTASA[®] make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, PENTASA[®] can cause side-effects although not everybody gets them.

Consult your doctor at once if you experience:

Common (1-10%): headache, diarrhoea, abdominal pain, nausea, vomiting, rash (including hives and redness)

Rare (0.01-0.1%): *inflammation of the heart muscle or area surrounding the heart,* inflammation of the pancreas, increased amylase. Amylase is an enzyme that helps digest carbohydrates. It is made in the pancreas and the glands that make saliva.

Very rare (<0.01%): increase in the number of eosinophils (a type of white blood cell) in the blood (as part of an allergic reaction), deficiency of all types of blood cells (including red blood cells, white blood cells and platelets) damage to peripheral nerves, allergic and fibrotic lung reactions (including shortness of breath, coughing, allergic inflamed lungs, lung disease), increased liver enzymes, bilirubin, liver toxicity (including liver inflammation*, liver scarring, liver failure), hair loss, muscle and joint pain, autoimmune diseases-like reactions, kidney

function impairment (including kidney inflammation*, kidney disease syndrome, kidney deficiency), Urine discoloration

Not known: Hypersensitivity reaction, medicine-induced fever

(*) The mechanism of mesalazine-induced heart muscle or area surrounding the heart inflammation, inflammation of pancreas, kidney and liver inflammation is unknown, but it might be of allergic origin.

It is important to note that several of these disorders can also be attributed to the inflammatory bowel disease itself.

Tell your doctor if you notice any of the side-effects listed or notice any other effects not listed.

You may report any side-effects or adverse drug reactions directly to the National centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550 or visiting the website: portal.bpfk.gov.my (Consumers → Reporting)

Storage and disposal of PENTASA[®]

-Storage

Store below 30°C. Store in the original package, as the product is sensitive to light

-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

White to tan , spotted, oblong, suppositories. Each suppository contains 1g of the active ingredient, mesalazine. PENTASA[®] suppositories 1g is packed in double aluminium foil

blister. Box of 4 blister x 7 suppositories.

-Ingredient

-Active Ingredient

Mesalazine (5-aminosalicylic acid – 5-ASA)

-Inactive ingredient

Povidone, macrogol 6000, magnesium stearate, talc

-MAL number

MAL19930530AZ

Manufacturer

Ferring International Center SA
St. Prex, Switzerland

Product Registration Holder

Ferring Sdn Bhd
21-6, Block B, Jaya One, No. 72-A,
Jalan Universiti, 46200 Petaling Jaya,
Selangor

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