

Package leaflet: Information for the user

PENTASA® 1 g Suppositories

mesalazine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have 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. See section 4.

What is in this leaflet:

1. What PENTASA Suppositories are and what they are used for
2. What you need to know before you use PENTASA Suppositories
3. How to use PENTASA Suppositories
4. Possible side effects
5. How to store PENTASA Suppositories
6. Contents of the pack and other information

1. WHAT PENTASA SUPPOSITORIES ARE AND WHAT THEY ARE USED FOR

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

PENTASA is used to treat inflammation in the gut caused by conditions such as ulcerative colitis. Sometimes ulcerative colitis only affects the back passage (rectum), this is known as ulcerative proctitis. PENTASA Suppositories are used to treat ulcerative proctitis and are intended for rectal use only.

The suppositories release the active ingredient slowly which then acts locally to reduce the inflammation and help relieve or stop the pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PENTASA SUPPOSITORIES

Do not use PENTASA Suppositories:

- if you are **allergic (hypersensitive)** to **mesalazine** or any of the other ingredients of this medicine (listed in Section 6)
- if you are **allergic** to other salicylates e.g. aspirin
- if you have **severe liver or kidney** problems

Warnings and precautions

Talk to your doctor or pharmacist before taking PENTASA Suppositories.

You should consult your doctor before taking these suppositories:

- if you experience any unexplained bleeding, bruising, skin rashes, fever or sore throat while using this medicine, stop using this medicine and seek medical advice as soon as possible
- if you currently have, or have previously had, liver or kidney disease
- if you are on medication that may affect kidney function e.g. azathioprine
- if you have ever had an allergy to a medication called sulphasalazine
- if you have lung problems, in particular asthma
- if you suddenly develop cramps, abdominal pain, fever, severe headache and rash. In such circumstances you should stop taking PENTASA immediately
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

If you suffer from kidney problems you will require regular check ups by your doctor.

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 PENTASA Suppositories.

Mesalazine may produce red-brown urine discoloration after contact with sodium hypochlorite bleach in the toilet water. It concerns a chemical reaction between mesalazine and bleach and is harmless.

Take special care with mesalazine:

Serious skin reactions including Drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) have been reported in association with mesalazine treatment. Stop using PENTASA Suppositories 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 PENTASA Suppositories

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

This is especially important if you are taking any of the following:

- **azathioprine** (used after transplantations or to treat autoimmune diseases)
- **6-mercaptopurine or thioguanine** (chemotherapy, used to treat leukaemia)
- certain agents that inhibit blood clotting (medicines for thrombosis or to thin your blood)

Pregnancy, breast-feeding and fertility

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.

There is limited experience with the use of mesalazine during pregnancy and breast-feeding. Blood disorders have been reported in newborns of mothers being treated with this medicine. The newborn may develop allergic reactions after breast-feeding, e.g. diarrhoea. If the newborn develops diarrhoea, breast-feeding should be discontinued.

Driving and using machines

This medicine is not known to affect the ability to drive and/or use machines.

3. HOW TO USE PENTASA SUPPOSITORIES

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

The suppository should be inserted into the back passage (rectum) only. It is intended to be left in place for as long as possible and is therefore best inserted before going to sleep.

Adults

To treat an attack of proctitis your doctor will usually prescribe one suppository twice daily for two to four weeks. To help prevent further attacks, the recommended dose is one to two suppositories daily.

How to insert the suppository

You should make sure that you empty your bowels before inserting the suppository.

- a. Tear along the perforation to remove one suppository blister from a blister strip.
- b. Remove the suppository from the blister before insertion. This is done by pushing the suppository through the printed foil.
- c. Insertion may be made easier if you moisten the suppository with water first.
- d. Insert the suppository gently and fully into the back passage. It may help to lie down on one side and raise the other knee.
- e. Remain still for a few minutes after insertion to help keep the suppository in place. If it comes out within 10 minutes, a new one should be inserted.

- f. Dispose of the empty blister safely and wash your hands.

If you use more PENTASA Suppositories then you should

If you accidentally use too many suppositories, you should go to your nearest emergency department or contact your doctor immediately. Take the pack and any remaining suppositories with you.

If you forget to use PENTASA Suppositories

If you forget to use a dose, use the next dose as soon as you remember, unless it is less than 6 hours until your next dose. Do not take a double dose to make up for the forgotten one.

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

4. POSSIBLE SIDE EFFECTS

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

Stop using PENTASA Suppositories 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.

There have been very few reports of a severe allergic reaction (including severe skin erosions that may affect the skin as the protective barrier of the body). The allergic reaction might lead to swelling of the face and neck and/or difficulty in breathing or swallowing. If this happens contact your doctor or nearest casualty department immediately.

The following common side effects affect between 1 and 10 of every 100 patients treated:

- diarrhoea
- abdominal pain
- nausea
- vomiting
- headache
- rash
- flatulence (passing wind)
- anal discomfort and irritation at the application site, itching and feeling of incomplete defecation (tenesmus)

The following rare side effects affect between 1 and 10 of every 10,000 patients treated:

- inflammation of some areas of the heart (myocarditis and pericarditis) which can cause shortness of breath and chest pain or palpitations (rapid or irregular heart beats)
- inflammation of the pancreas (symptoms include back and/or stomach pain)
- increased amylase (enzyme that helps digest carbohydrates)
- dizziness
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)

The following very rare side effects affect less than 1 of 10,000 patients treated:

- anaemia and other blood disorders (decrease in the numbers of certain blood cells, which can cause unexplained bleeding, bruising, fever or sore throat)
- liver disorders (symptoms include jaundice (yellowing of the skin and/or eyes) and/or pale bowel motions)
- kidney disorders (symptoms include blood in the urine and/or oedema (swelling due to build up of fluid))
- peripheral neuropathy (a condition affecting the nerves of the hands and feet, symptoms include tingling and numbness)
- allergic and fibrotic lung reactions, inflammation of the lining of the lungs or lung scarring (symptoms include coughing, bronchospasm, chest discomfort or pain on breathing, breathing difficulties, bloody and/or excessive phlegm)
- pancolitis (a kind of inflammatory bowel disorder (IBD) that affects the entire internal lining of the large bowel)
- hair loss (this is reversible)
- muscle or joint pain

- inflammation which can affect different parts of the body such as joints, skin, kidneys, heart etc. (symptoms include painful joints, fatigue, fever, abnormal or unexplained bleeding (e.g. nose bleeds), bruising, purple discolouration of the skin (including severe skin erosions and severe blistering that may affect the skin as the protective barrier of the body))
- semen with a low concentration of sperm (oligospermia) (this is reversible)
- severe diarrhoea and abdominal pain because of an allergic reaction to this medicine within the bowel.
- allergic reactions and fever may occasionally occur.

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

- kidney stones and associated kidney pain (see also section 2)
- change in urine colour.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PENTASA SUPPOSITORIES

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

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. CONTENTS OF THE PACK AND OTHER INFORMATION

What PENTASA Suppositories contain

Each suppository contains 1 g of the active ingredient, mesalazine. The other ingredients are povidone, magnesium stearate, macrogol 6000 and talc.

What PENTASA Suppositories look like and contents of the pack

The suppositories are white to tan, spotted, oblong suppositories. Each carton contains 28 suppositories presented in blister strips of 7 suppositories per strip and 30 finger protectors.

Parallel Product Authorisation holder

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