Package Leaflet: Information for the user
PENTASA® 500 mg prolonged-release tablets

mesalazine

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. See section 4.

What is in this leaflet:

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

1. What PENTASA Tablets are and what they are used for

The name of this medicine is PENTASA 500 mg Prolonged Release Tablets. Each tablet contains mesalazine 500 mg as the active ingredient. Mesalazine belongs to a group of medicines called salicylates.
PENTASA is used to treat mild to moderate inflammation of the gut caused by conditions called ulcerative colitis or Crohn's disease. It can also be used to control these conditions and prevent them from coming back. The tablets 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 take PENTASA Tablets

Do not take PENTASA Tablets:

- 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 any 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 Tablets.

You should consult your doctor before taking these tablets:

- 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 any 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 Tablets.

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 Tablets 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 Tablets
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 auto-immune 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, breastfeeding 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 using 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 take PENTASA Tablets

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

PENTASA Tablets should be taken by mouth; they must not be crushed or chewed. To help you swallow the tablets, you may disperse them in a small quantity of cold water (approximately 50 ml). Stir and drink immediately.

Adults
To treat an attack of ulcerative colitis your doctor will usually prescribe up to eight 500 mg tablets a day to be taken either once daily or in two or three divided doses. To help prevent further attacks of ulcerative colitis, the recommended dose is 2 g mesalazine (i.e. four 500 mg tablets) once daily.

To treat an attack of Crohn's disease your doctor will usually prescribe up to eight 500 mg tablets a day in two or three divided doses. To help prevent further attacks of Crohn's disease, your doctor will usually prescribe up to eight 500 mg tablets a day in two or three divided doses.

Children aged 6 years and over
Ulcerative colitis and Crohn's disease:
The dose for children will be calculated by your doctor and depends on the child's weight. It is generally recommended that half the adult dose is given to children up to 40 kg of body weight and the normal adult dose to children above 40 kg of body weight.

If you take more PENTASA Tablets than you should
If you accidentally take too many tablets, you should go to your nearest emergency department or contact your doctor immediately. Take the pack and any remaining tablets with you.

If you forget to take PENTASA Tablets
If you forget to take a dose, take the next dose as soon as you remember, unless it is less than 3 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 Tablets 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)

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))
- change in urine colour
- 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)

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 Tablets
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 Tablets contain

The active ingredient is mesalazine. Each prolonged-release tablet contains 500 mg mesalazine.
The other ingredients are povidone, ethylcellulose, microcrystalline cellulose, magnesium stearate and talc.

What PENTASA Tablets look like and the contents of the pack
The tablets are white-grey to pale brown, specked, round tablets, scored and marked '500 mg' on one side and 'PENTASA' on the other side. Each carton contains 100 tablets presented in blister strips of 10 tablets per strip.

Manufacturer:

Ferring GmbH, Wittland 11, D-24109 Kiel, Germany.

The product is procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Number: PPA0465/450/002

Pentasa is a registered trademark of Ferring B.V.

This leaflet was last revised in July 2023.