

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PENTASA® 500 mg prolonged-release tablets

Mesalazine

Sugar free

Read all of this leaflet carefully before you start taking PENTASA® 500 mg tablets

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- PENTASA® 500 mg tablets have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PENTASA® 500 mg is and what it is used for
2. What you need to know before you take PENTASA® 500 mg
3. How to take PENTASA® 500 mg
4. Possible side effects
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1. What PENTASA® 500 mg is and what it is used for

PENTASA® 500 mg tablets are used to treat mild to moderate attacks of ulcerative colitis and to help maintain freedom from further attacks. Ulcerative colitis is a disease associated with inflammation, ulcers and sores in the bowel causing bleeding, stomach pain, and diarrhoea.

The active ingredient in this medicine is mesalazine. It is an anti-inflammatory medicine, chemically similar to aspirin, and is thought to work by reducing inflammation in the bowel.

2. What you need to know before you take PENTASA® 500 mg

Do not take PENTASA® 500 mg:

- if you are hypersensitive (allergic) to mesalazine, aspirin-like medicines or any of the other ingredients of PENTASA® 500 mg tablets (listed in section 6).
- if you have a severe kidney or liver problem.

Warnings and precautions

Take special care with PENTASA® 500 mg:

- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking mesalazine as contained in PENTASA® 500 mg, tell your doctor before taking PENTASA® 500 mg. Serious skin reactions including Drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and Toxic Epidermal Necrolysis (TEN) have been reported in association with PENTASA® 500 mg. Stop taking PENTASA® 500 mg and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions (see section 4).
- If you suddenly develop abdominal cramps, abdominal pain, fever, severe headache, and skin rashes, which may be signs of a hypersensitivity reaction, stop taking PENTASA® 500 mg and seek medical advice immediately.
- If you experience chest pains, rapid or irregular heartbeat, tiredness, and shortness of breath, which may be signs of a hypersensitivity reaction affecting your heart, stop taking PENTASA® 500 mg and contact your doctor immediately.
- If you develop unexplained bleeding (e.g., nose bleeds), bruises, purple discolouration of the skin, sore throat, and fever, which may be signs of serious blood disorders, stop taking PENTASA® 500 mg and contact your doctor immediately.
- If you have a medical condition that can make you prone to bleeding.
- If you have kidney or liver problems.
- If you have a history of lung disease, in particular asthma.

- If you are on medication that may affect your kidney function e.g., non-steroidal anti-inflammatory medicine (NSAIDs) such as aspirin, and azathioprine.
- If you are allergic to sulphasalazine (due to the risk of allergy to salicylates).
- If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears contact your doctor immediately.
- Kidney stones may develop with use of PENTASA[®] 500 mg. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amounts of liquid during treatment with PENTASA[®] 500 mg.
- Mesalazine (as contained in PENTASA[®] 500 mg) 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.

Your doctor will draw blood and test your liver and kidney function before and during treatment with PENTASA[®] 500 mg tablets.

If you are about to start any new treatment or medication, tell your doctor, dentist and pharmacist that you are taking PENTASA[®] 500 mg tablets.

Caution is advised during the use of PENTASA[®] 500 mg tablets in the elderly.

Children and adolescents

PENTASA[®] 500 mg is not recommended for children younger than 6 years because efficacy and safety has not been established.

Other medicines and PENTASA[®] 500 mg

Always tell your healthcare provider if you are taking, or have recently taken, any other medicine. (This includes all complementary or traditional medicines.) The use of PENTASA[®] 500 mg tablets with these medicines may cause undesirable interactions.

Mesalazine belongs to a group of medicines called salicylates that may interfere with the following types of medicines:

- azathioprine, used to suppress the immune system
- mercaptopurine, used to treat leukaemia
- thioguanine, used to treat leukaemia
- warfarin, a blood thinner used to reduce the formation of blood clots.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking PENTASA[®] 500 mg tablets. There is limited experience with the use of PENTASA[®] 500 mg during pregnancy and breastfeeding and should therefore be used with caution. Preterm birth, stillbirth, and low birth weight have been reported, however, these adverse pregnancy outcomes are also associated with active inflammatory bowel disease. Blood disorders have been reported in new-borns of mothers being treated with PENTASA[®] 500 mg tablets.

The new-born may develop allergic reactions after breastfeeding e.g., diarrhoea. If the new-born develops diarrhoea, breastfeeding should be discontinued.

Animal studies show that mesalazine does not affect the ability to have babies in males or females.

Driving and using machines

PENTASA[®] 500 mg tablets are not known to affect your ability to drive a car or operate machinery.

It is not always possible to predict to what extent PENTASA[®] 500 mg may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PENTASA[®] 500 mg affects you.

3. How to take PENTASA[®] 500 mg

Do not share medicines prescribed for you with any other person.

Always take PENTASA[®] 500 mg tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

PENTASA® 500 mg tablets must not be chewed or crushed. The tablet may be swallowed whole or, to help you swallow the tablets, you may disperse them in a small quantity of cold water (approximately 50 ml). Stir and drink immediately.

The dose and directions of PENTASA® 500 mg tablets will be different for different patients and may depend on other medicines also being taken.

How much to take:

Use as directed by your doctor.

Adults:

To treat an attack of colitis, your doctor will prescribe a dose of up to 4 g mesalazine a day administered as eight tablets of PENTASA® 500 mg, once a day or in divided doses.

To help maintain freedom from further attacks, your doctor will usually prescribe 2 g mesalazine a day administered as four tablets of PENTASA® 500 mg once daily or in divided doses.

Children 6 years of age and older:

For an attack of ulcerative colitis and to help maintain freedom from further attacks, 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. The total dose should not exceed 2 g/day (recommended adult dose).

How long to take it:

Your doctor will tell you how long your treatment with PENTASA® 500 mg tablets will last. Do not stop treatment early because this medicine helps to control your condition but does not cure it. It is important to keep using your medicine even if you feel well.

If you have the impression that the effect of PENTASA® 500 mg tablets is too strong or too weak, tell your doctor or pharmacist.

If you take more PENTASA® 500 mg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre immediately. Take this leaflet and any tablets with you, so that the doctor knows what you have taken.

If you forget to take PENTASA® 500 mg

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally. Do not take a double dose to make up for forgotten individual doses. If you are not sure what to do, ask your doctor or pharmacist.

If you stop taking PENTASA® 500 mg

Do not stop using PENTASA® 500 mg tablets or lower the dosage without checking with your doctor first. If you stop using it suddenly, your condition may worsen.

4. Possible side effects

PENTASA® 500 mg tablets can have side effects.

Not all side effects reported for PENTASA® 500 mg tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PENTASA® 500 mg, please consult your healthcare provider for advice.

Allergic reactions may occur and are very serious.

If any of the following happens, stop taking PENTASA® 500 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden signs of allergic reactions such as rash, itching or hives, shortness of breath, coughing, chest tightness or wheezing, dizziness, fainting, rapid or weak heartbeat, swelling of the limbs, face, lips, mouth and throat which may cause difficulty swallowing or breathing,
- severe stomach cramps and/or pain, bloody diarrhoea, fever, severe headache and skin rash,

- 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,
- bruising easily, unusual bleeding (e.g., nosebleeds), or frequent signs of infection such as fever, chills, sore throat and mouth ulcers (signs of blood disorders),
- chest pain sometimes spreading to the neck and shoulders, with fever, shortness of breath, excess tiredness and rapid or irregular heartbeat (signs of heart problems),
- a change in the colour or amount of urine produced (signs of kidney problems).

These are all very serious side effects. If you have them, you may have had a serious reaction to PENTASA® 500 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- diarrhoea
- abdominal pain
- nausea or vomiting
- rash
- flatulence (passing wind).

Less frequent side effects:

- inflammation of the pancreas (symptoms include back and/or stomach pain)
- increased amylase in your blood and/or urine (enzyme that helps digest carbohydrates)
- dizziness
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)
- anaemia which is characterised by a decrease in the number of red blood cells (symptoms may include extreme tiredness, and weakness)

- liver disorders including an increase in liver enzymes, no or reduced flow of bile, inflammation, scarring and failure of the liver (symptoms may include jaundice characterised by yellowing of the skin and/or eyes, and/or pale bowel motions)
- kidney disorders including inflammation of the kidneys (symptoms may include blood in the urine, and/or swelling due to build-up of fluid)
- lupus erythematosus syndrome which is an autoimmune disorder causing inflammation in different parts of the body such as joints, skin, kidneys, heart, blood vessels, and brain
- numbness, tingling or weakness of the arms and legs (peripheral neuropathy)
- allergic and fibrotic lung reactions, inflammation of the lining of the lungs or lung scarring (symptoms may include coughing, bronchospasm, chest discomfort or pain on breathing, breathing difficulties, bloody and/or excessive phlegm)
- pancolitis which is a kind of inflammatory bowel disorder (IBD) that affects the entire internal lining of the large bowel called (symptoms may include exhaustion, abnormal weight loss, fever, pain and cramps in your stomach and abdomen, strong and frequent bowel movement that may contain blood)
- fever
- hair loss (reversible)
- muscle pain
- joint pain
- semen with a low concentration of sperm (oligospermia) (this is reversible).

Frequency not known:

- if you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears. These could be symptoms of increased pressure within your skull (idiopathic intracranial hypertension)
- kidney stones and associated kidney pain (see also section 2)
- change in urine colour (see also section 2).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PENTASA® 500 mg.

5. How to store PENTASA® 500 mg

- Store all medicines out of reach of children.
- Store at or below 25 °C in the original package. Protect from light. Do not freeze.
- Do not use after the expiry date stated on the carton.
- Please return expired medicine or partially used medicine to your pharmacist for safe disposal.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What PENTASA® 500 mg contains:

- The active substance is mesalazine; each tablet contains 500 mg mesalazine.
- The other ingredients are magnesium stearate, talc, ethylcellulose, povidone, microcrystalline cellulose.

What PENTASA® 500 mg looks like and contents of the pack

White-grey to pale-brown, speckled round tablets.

Breakmark and embossing: 500 mg on one side, PENTASA on the other side.

Pack sizes of 100 tablets in double aluminium foil blisters, each strip containing 10 tablets; packed in an outer carton.

Holder of Certificate of Registration

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