

PENTASA® Slow Release Tablets 500mg (mesalazine)

Patient Information

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What PENTASA is and what it is used for

The name of this medicine is Pentasa Slow Release Tablets. Each tablet contains mesalazine 500mg 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 a condition called ulcerative colitis. It can also be used to control the condition and prevent it 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. Before you take PENTASA

Do Not take Pentasa if you :

- are **allergic** to mesalazine or any of the other ingredients in Pentasa (see section 6)
- are **allergic** to any other salicylates e.g. aspirin
- have **severe liver or kidney** problems

Take special care with Pentasa

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.
- You experience any chest pain, an increased heartbeat and excess tiredness while using this medicine, **stop using** this medicine and seek medical advice as soon as possible.
- You suddenly develop abdominal cramps, abdominal pain, fever, severe headache and rash, **stop using** this medicine and seek medical advice immediately.
- you have lung problems, in particular asthma.
- you currently have, or have previously had liver or kidney disease
- you are on any medication that may affect kidney function e.g. azathioprine
- you have ever had an allergy to a medication called sulphasalazine

- 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.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using 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 4

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

You should make sure that you don't become dehydrated, while you are taking this medicine. This can occur after severe or prolonged attacks of vomiting and/or diarrhoea, high fever or heavy sweating. If this does occur, you should speak to a doctor or pharmacist for advice as soon as possible.

Taking with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important if you are taking any of the following :

- Azathioprine, 6-mercaptopurine or thioguanine
- Certain agents that inhibit blood clotting (medicines for thrombosis or to thin your blood, e.g. warfarin)

Pregnancy and Breastfeeding

If you are pregnant, are planning to become pregnant or are breastfeeding you should speak to your doctor or pharmacist for advice before taking this medicine.

There is limited experience with the use of mesalazine during pregnancy and breast-feeding. The newborn may develop allergic reactions after breast-feeding, e.g. diarrhoea. If the newborn develops diarrhoea, breast-feeding should be discontinued.

3. How to take PENTASA

Always take Pentasa exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be taken by mouth either whole or broken up, they should not be crushed or chewed. If you have difficulty swallowing the tablets you can disperse them in a small quantity of cold water (approximately 50ml) then stir and drink immediately.

Adults

To treat an attack of colitis, your doctor will usually prescribe a dose of up to 4g mesalazine, to be taken as eight 500mg tablets once a day or in two or three divided doses.

To help prevent further attacks, your doctor will usually prescribe a dose of 2g mesalazine, to be taken as four 500mg tablets once a day.

Children 6 years of age and older:

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 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

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, Pentasa can cause side effects, although not everyone gets them.

STOP using Pentasa 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. These serious skin rashes can be preceded by fever and flu-like symptoms.
- itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing or wheeziness (signs of an allergic reaction).
- unexplained bleeding, bruising, skin rashes, fever or sore throat (signs of a blood disorder).
- a change in the colour or amount of urine produced (signs of kidney problems).

If you experience any of the above side effects you should contact your doctor or go to the nearest hospital emergency department immediately.

Other side effects include:

Rare side effects

(affecting less than 1 in 1,000 patients) include:

- vomiting
- stomach pain
- nausea
- diarrhoea
- headache
- inflammation of the heart or area surrounding the heart
- dizziness
- flatulence (passing wind)
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

Very rare side effects

(affecting less than 1 in 10,000 patients) include:

- raised liver enzymes
- hair loss (reversible)
- joint and muscle pain
- allergic reactions and fever
- lupus erythematosus (an auto-immune disorder effecting the skin)
- semen with a low concentration of sperm (oligospermia) (this is reversible)
- blood disorders (e.g. low levels of red blood cells)
- tingling or numbness in the hands and feet
- allergic and fibrotic lung reactions (including breathing problems)
- changes in kidney function or kidney failure
- inflammation of the pancreas

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store PENTASA

Do not store above 25°C.

Store in original packaging and do not use after the expiry date detailed on the pack.

Keep out of sight and reach of children.

Return any old or unused medicines to your pharmacist for disposal.

6. Further information

What Pentasa contains

Each tablet contains 500mg of the active ingredient, mesalazine. It also contains the following inactive ingredients: povidone, ethylcellulose, microcrystalline cellulose, magnesium stearate and talc.

What Penasa looks like and the contents of the pack

The tablets are white/grey to pale brown, speckled, round tablets, scored and marked '500mg' on one side and 'PENTASA' on the other side. Each carton contains 100 tablets presented in blister strips of 10 tablets per strip.

Marketing Authorisation Holder:

Ferring Pharmaceuticals Ltd.,
Drayton Hall, Church Road, West Drayton, UB7 7PS, (UK)

Manufactured by:

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

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This leaflet was last revised in January 2021.

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