

Pentasa® Suppositories 1g

(mesalazine)

Patient Information Leaflet

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. Do not pass it on to others. It may harm them, even if their symptoms 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.

Your medicine is called Pentasa Suppositories 1g but will be referred to as Pentasa throughout the rest of this leaflet.

What is in this leaflet:

- 1 What Pentasa is and what it is used for
- 2 What you need to know before you use Pentasa
- 3 How to use Pentasa
- 4 Possible side effects
- 5 How to store Pentasa
- 6 Contents of the pack and other information

1 What Pentasa is and what it is used for

Each Pentasa contains mesalazine 1g 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 is used to treat ulcerative proctitis and is 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

Do Not use Pentasa if you:

- * are **allergic (hypersensitive) to mesalazine** or any of the other ingredients of this medicine (see section 6)
- * are **allergic to other salicylates e.g. acetylsalicylic acid**
- * have **severe liver and/or kidney** problems

Warnings and precautions

Talk to your doctor or pharmacist before using these suppositories if you:

- * are allergic to **sulphasalazine** (risk of allergy to salicylates)
- * currently have or have previously had **liver** or **kidney** disease
- * have a medical condition that can make you prone to **bleeding**
- * are on **medication** that may affect **kidney** function e.g. non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin
- * have lung problems, in particular asthma
- * suddenly develop abdominal cramps, abdominal pain, fever, severe headache and rash. In such circumstances you should stop taking Pentasa immediately.
- * 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 have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

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) and toxic epidermal necrolysis (TEN) have been reported in association with mesalazine treatment. Stop using Pentasa and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears contact your doctor immediately.

While you are on treatment with this medicine, your doctor will normally arrange blood and urine tests to check your kidney function especially at the beginning of treatment.

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

Other medicines and Pentasa

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** (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, e.g. warfarin)

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 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 use Pentasa

For Adult use only, not recommended in children.

Always use Pentasa exactly as your doctor has told you. You should 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. To treat an attack of proctitis your doctor will usually prescribe one suppository to be used daily for two to four weeks. To help prevent further attacks it may be used for longer.

How to insert the suppository

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

- Tear along the perforation to remove one suppository blister from a blister strip
- Put a protector on the finger with which you will insert the suppository
- Remove the suppository from the blister before insertion. This is done by pushing the suppository through the printed foil
- Insertion may be made easier if you moisten the suppository with water first
- Insert the suppository gently and fully into the back passage. It may help to lie down on one side and raise the other knee.
- 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
- Dispose of the empty blister and used finger protector safely and wash your hands.

If you use more Pentasa than 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

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 use 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.

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Patient Information Leaflet (continued)

4 Possible side effects

Like all medicines, Pentasa can cause side effects, although not everyone gets them. Following rectal administration local reactions such as itching, rectal discomfort and urge may occur.

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, widespread rash, fever and enlarged lymph nodes. 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 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.

The following common side effects may affect up to 1 in 10 people:

- * diarrhoea
- * abdominal pain
- * nausea
- * vomiting
- * headache
- * rash
- * flatulence (passing wind)
- * rectal discomfort,
- * irritation at the site of application

The following rare side effects may affect up to 1 in 1,000 people:

- * 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 may affect up to 1 in 10,000 people:

- * 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 discoloration 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.
- * 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).

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Do not store above 25°C.

Store in original package in order to protect from moisture.

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

If your doctor tells you to stop taking this medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor advises you to.

If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.

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.

6 Contents of the pack and other information

What Pentasa contains

Each suppository contains mesalazine 1g.
Other ingredients povidone, macrogol 6000, magnesium stearate and talc.

What Pentasa looks like and the contents of the pack

The suppositories are oblong, compressed, white to light tan speckled suppositories. Each carton contains 28 Suppositories presented in blister strips of 7 suppositories per strip, together with 28 finger protectors for use when inserting the suppository.

Manufacturer and Licence Holder

This medicine is manufactured by Ferring GmbH, Kiel, Germany and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

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