

PENTASA® Suppositories 1g

(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 Suppositories. Each suppository 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 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. Before you take PENTASA

Do Not use 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 using these suppositories if:

- 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
- 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
- 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.

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 does occur, you should speak to a doctor or pharmacist for advice as soon as possible.

While you are using Pentasa your doctor may occasionally want to check your kidney function.

Using 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 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.

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

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. 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, wheeziness or coughing (signs of an allergic reaction).
- skin disorder due to an allergic reaction or infection (Erythema Multiforme or Stevens-Johnson syndrome). Symptoms include severe rash, blisters or red splotches on the skin.
- unexplained bleeding, bruising, skin rashes, fever or sore throat (signs of blood disorder).
- change in colour or amount of urine produced (signs of kidney problems).
- Chest pain, an increase in heartbeat or excess tiredness (signs of heart problems).
- Inflammation of the liver or liver failure, symptoms include yellowing of the eyes and/or skin (Jaundice), dark urine, stomach pain, fever, feeling tired or nausea.
- Inflammation of the pancreas, symptoms include back and/or stomach pain, fever, nausea and vomiting.
- ulcerative colitis involving the entire large intestine.

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

Common side effects

(may affect up to 1 in 10 people)

- rash with or without itching

Rare side effects

(may affect up to 1 in 1,000 people)

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

Very rare side effects

(may affect up to 1 in 10,000 people)

- raised liver enzymes
- hair loss (reversible)
- joint and muscle pain
- allergic reactions and fever
- lupus erythematosus (an auto-immune disorder affecting the skin)
- skin rash or blisters e.g. Erythema Multiforme or Stevens-Johnson syndrome
- 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 suppository contains 1g of the active ingredient, mesalazine. It also contains the following inactive ingredients: povidone, magnesium stearate, macrogol 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.

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.

PENTASA Suppositories 1g PL 3194/0045

This leaflet was last revised in January 2021.

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