

PACKAGE LEAFLET: INFORMATION FOR THE USER

PENTASA®

Sachet 2g prolonged release granules

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. 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 effect, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. WHAT PENTASA SACHET IS AND WHAT IT IS USED FOR

PENTASA Sachet is used for the treatment of mild to moderate attacks of ulcerative colitis and to help maintain freedom from further attacks.

Ulcerative colitis is an inflammatory bowel disease in which the lining of the intestine becomes inflamed and develops many tiny breaks in its surface (ulcers) which may bleed.

PENTASA Sachet contains granules that slowly release the active ingredient (mesalazine). This helps reduce the inflammation and the painful symptoms.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PENTASA SACHET

Do not take PENTASA Sachet

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Pentasa Sachet:

- if you are allergic to sulphasalazine (risk of allergy to salicylates)
- if you currently have or have previously had liver or kidney disease
- if you have a medical condition that can make you prone to bleeding
- if you have an active peptic ulcer (stomach ulcer or duodenal ulcer)
- if you are on medication that may affect kidney function e.g. Non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin
- if you have lung problems, in particular asthma
- if you suddenly develop abdominal cramps, abdominal pain, fever, severe headache and rash. In such circumstances you should stop taking Pentasa 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.

Other medicines and Pentasa Sachet

Tell your doctor or pharmacist if you are using, or have recently used, 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).

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 taking 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 SACHET

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

Adults:

To treat an attack of colitis, your doctor will usually prescribe a dose of up to 4 g mesalazine a day to be taken either once a day or in divided doses. This may be taken as two PENTASA Sachet 2g once a day. PENTASA Sachet 1g might also be used to provide the dose that is most suited to you.

To help maintain freedom from further attacks, your doctor will usually prescribe 2 g mesalazine a day administered as one PENTASA Sachet 2g or two PENTASA Sachet 1g once daily.

Use in children and adolescents

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.

You should take the granules orally (by mouth), immediately after opening the sachet, as described below. Do not chew the granules.

1. Open the foil sachet.
2. Empty the contents of the sachet onto the tongue.
3. Wash the granules down immediately with some water or orange juice ensuring that none remain in the mouth.

If you take more PENTASA Sachet than you should

In the event of overdose, contact your doctor or nearest casualty department immediately.

If you forget to take PENTASA Sachet

If you have forgotten to take a dose, then take it as soon as you remember, and then take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

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.

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 (Quincke's oedema). If this happens contact your doctor or nearest casualty 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)

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)
- dizziness

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)
- 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))
- accumulation of fluid around the heart (pericardial effusion) which can cause chest pain or pressure
- 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

There have been very few reports of benign intracranial hypertension (build up of fluid around the brain) in adolescents. Symptoms include headache, nausea, vomiting, and/or visual or hearing disturbances.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PENTASA SACHET

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and foil sachet. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What PENTASA Sachet contains

Each sachet contains mesalazine 2g. The other ingredients are ethylcellulose and povidone.

What PENTASA Sachet looks like and contents of the pack

This medicine contains prolonged release granules. The granules are white-grey to pale white-brown. This medicine is presented in foil sachets in packs of 60.

Product Authorisation Number:

PPA 465/235/2

Product procured from within the EU, repackaged and distributed by the parallel product authorization holder and repackaged by:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

Manufacturer

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

Pentasa is a registered trademark of Ferring B.V.

This medicinal product is authorised in the Member States of the EEA under the following names:

Quintasa Sachet: Denmark

Pentasa Sachet: Germany (1g), Ireland, Spain, Sweden, United Kingdom

Pentasa Xtend: Germany (2g)

Pentasa: Slovenia, Cyprus, Greece

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