Package Leaflet: Information For The User

Pentasa® Sachet 1g prolonged release granules
Pentasa® Sachet 2g prolonged release granules
Pentasa® Sachet 4g 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. See section 4

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.

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- 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

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

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 mesalazine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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 auto-immune 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 one Pentasa Sachet 4 g or two Pentasa Sachet 2g once daily. 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 and wash the granules down immediately with some water or orange juice ensuring that none remain in the mouth

OR

3. Mix the entire content of the sachet with yogurt. Intake immediately without chewing on the granules.

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.

Serious side effects
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.

Tell your doctor immediately if you experience strong or recurrent headache, disturbed vision, or ringing or buzzing on the ears. These could be symptoms of increased pressure within your skull (idiopathic intracranial hypertension). This very rare side effect may affect up to 1 in 10,000 people.

Stop using mesalazine 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.

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).
- 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))
- 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.

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 HPRA Pharmacovigilance, Website: www.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 throw away medicnes you no longer use. These measures will help protect the environment.

6. Content Of The Pack And Other Information

What Pentasa Sachet contains

The active substance is mesalazine
Each sachet contains mesalazine 1 g, 2 g or 4 g.
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 aluminium foil sachets in packs of:
Sachet 1g: 50, 100 or 150
Sachet 2g: 10, 60 or 120
Sachet 4g: 20, 30, 50 or 100

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Ferring Ireland Ltd.
United Drug House, Magna Drive, Magna Business Park,
Citywest Road, Dublin 24, Ireland

Manufacturer
Ferring GmbH
Wittland 11
D-24109 Kiel
Germany

This medicine is authorised in the Member States of the Europe Economic Area under the following names:

Quintasa Sachet:	Denmark
Pentasa Sachet:	Germany (1g), Ireland, Spain, Sweden
Pentasa Xtend:	Germany (2g)
Pentasa:	Slovenia, Cyprus, Greece

This leaflet was last revised in June 2026.

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