Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Pentasa

Prolonged release granules, 1 gram, 2 grams and 4 grams

Composition:
Each sachet of Pentasa **prolonged release granules** 1 gr contains:
1000 mg of mesalazine
Each sachet of Pentasa **prolonged release granules** 2 gr contains:
2000 mg of mesalazine
Each sachet of Pentasa **prolonged release granules** 4 gr contains:
4000 mg of mesalazine

Inactive ingredients: See section 6, 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult with your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Pentasa granules 1 gr, 2 gr and 4 gr: Anti-inflammatory medicine for the treatment of ulcerative colitis or Crohn's disease.

Therapeutic group: Anti-inflammatory medicine belonging to the group of medicines called salicylates.

2. Before using this medicine

Do not use this medicine if you:

- are sensitive (allergic) to mesalazine or to any of the other ingredients of this medicine (see section 6).
- are sensitive (allergic) to other salicylates, such as acetylsalicylic acid.
- have severe liver and/or kidney problems.

Special warnings about using this medicine

Before taking this medicine, consult with your doctor if you:

- are allergic to sulphasalazine (risk of allergy to salicylates).
- have or previously had liver or kidney disease.
- have a medical condition that may make you prone to bleeding.
- have an active peptic ulcer (gastric or duodenal ulcer).
- are taking medicines that may affect kidney function, such as non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin.
- have lung problems, particularly asthma.
- **suddenly develop abdominal cramps, abdominal pain, fever, severe headache and rash. In such instance, immediately stop taking the medicine.**

Kidney stones may develop during the treatment with mesalazine. Symptoms may include pain in the sides of your abdomen and blood in urine. Drink a sufficient amount of liquids during the treatment with mesalazine.

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

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis have been reported in association with mesalazine treatment. Stop taking the medicine and contact your doctor immediately if you have any of the symptoms of serious skin reactions such as those described in section 4.

Tests and follow-up
During the course of treatment with this medicine (particularly at the beginning), your doctor may arrange for you to take blood and urine tests in order to check your kidney function.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist, particularly if you are taking:

- anticoagulants (to treat thrombosis or to thin your blood).
- azathioprine (used after transplants or to treat auto-immune diseases).
- 6-mercaptopurine or thioguanine (chemotherapy medicines usually used to treat leukemia).

Pregnancy and breastfeeding
If you are pregnant or are breastfeeding, consult with your doctor or pharmacist before using this medicine. There is limited experience with the use of mesalazine during pregnancy and during the period of breastfeeding. Blood disorders have been reported in infants being breastfed by mothers being treated with Pentasa. Infants may develop an allergic reaction after breastfeeding, such as diarrhea. If your baby is being fed by breastmilk and develops diarrhea, stop breastfeeding.

Driving and using machines
This medicine has no known effect on the ability to drive and/or operate machines.

3. How to use this medicine?
Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dosage or the mode of treatment with a medicinal product. The dosage and mode of treatment will be determined by your doctor only. The customary dosage is usually:

– Ulcerative colitis:
  Treatment of a severe attack: up to 4 gr per day, which may be taken once per day or in divided doses.
  Maintenance treatment: 2 gr once per day.

– Crohn’s disease:
  Treatment of a severe attack and maintenance treatment: up to 4 gr per day in divided doses.

Use in children above 6 years of age and in adolescents:
The recommended dosage will be calculated by the treating physician and depends on the child’s weight. It is generally recommended to give children who weigh up to 40 kg half of the recommended dosage for adults. The dosage normally suitable for adults may be given to children weighing more than 40 kg.

Do not exceed the recommended dosage.

How to use:
Do not chew!

1. Open the foil sachet.
2. Empty the contents of the sachet directly into the mouth.
3. Swallow the medicine with the needed quantity of water or juice.

If you have accidentally taken a higher dose or if a child has accidentally swallowed some of the medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
If you forgot to take this medicine at the scheduled time, take the dose as soon as you remember; but never take two doses together!

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop the treatment with this medicine without consulting with your doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult with your doctor or pharmacist.

4. Side effects

Like with all medicines, using Pentasa granules may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

There have been a few reports of a severe allergic reaction (including severe skin erosions that may affect the skin's function as the protective layer of the body). An allergic reaction may cause swelling of the face and neck and/or difficulties breathing or swallowing (Quincke´s edema). If this happens, immediately see a doctor or go to a hospital emergency room.
Stop using this medicine and contact your doctor immediately in the event of:

- reddish non-elevated, target-like or circular patches on the body, generally with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious effects can be preceded by fever and flu-like symptoms.

Additional side effects

<u>Common side effects – affecting 1-10 in 100 users:</u>

- diarrhea
- abdominal pain
- nausea
- vomiting
- headache
- rash
- flatulence

<u>Rare side effects – affecting 1-10 in 10,000 users:</u>

- inflammation of the heart (myocarditis, pericarditis), which may cause shortness of breath, chest pain and palpitations (rapid or irregular heartbeat)
- inflammation of the pancreas (symptoms include back and/or abdominal pain)
- elevated level of amylase (enzyme that helps digest carbohydrates)
- dizziness
- increased sensitivity of the skin to sunlight and ultraviolet light

<u>Very rare side effects – affecting less than one in 10,000 users:</u>

- anemia and other blood disorders (decrease in particular blood cell counts, which may cause unexplained bleeding, bruising, fever or sore throat)
- liver disorders (symptoms include yellowing of the skin and/or eyes, pale stools)
- kidney disorders (symptoms include blood in urine and/or edema (swelling of the body due to a build-up of fluids))
- peripheral neuropathy (symptoms include tingling and numbness of the limbs)
- allergic and fibrotic lung inflammation (symptoms include cough, bronchospasm, chest discomfort, pain when inhaling, breathing difficulties, bloody and excessive phlegm)
- pancolitis (a type of inflammatory bowel disorder (IBD) that affects the entire inner lining of the large intestine)
- hair loss (reversible)
- muscle or joint pain
- inflammations that affect different parts of the body, such as joints, skin, kidneys, heart, etc. (symptoms include joint pain, fatigue, fever, abnormal or unexplained bleeding (such as a nose bleed), bruising, purple discoloration of the skin (including severe skin erosions and blisters that may affect the skin's function as the protective layer of the body))
- retention of fluids around the heart that may cause chest pain or pressure
- change in urine color
- decrease in sperm count in semen (reversible)
- severe diarrhea and abdominal pain due to an allergic reaction to the medicine in the intestine
- Allergic reactions and fever may occur occasionally.

Side effects of unknown frequency (cannot be estimated from the available information):
- kidney stones and associated kidney pain (see also section 2).

There have been a few reports of intracranial hypertension (build-up of fluid around the brain) in adolescents. The symptoms are headache, nausea, vomiting and/or visual disturbances or hearing disturbances.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult with your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?
- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions
- Store below 25˚C in the original package.

6. Additional information
In addition to the active ingredient, this medicine also contains: ethylcellulose, povidone.

Each sachet contains prolonged release granules that are white-grey to pale brown in color.

Pentasa prolonged release granules 2 grams are marketed in a pack containing 60 or 120 sachets.
Pentasa prolonged release granules 1 gram are marketed in a pack containing 50, 100, 120 or 150 sachets.
Pentasa prolonged release granules 4 grams are marketed in a pack containing 30 sachets.

Not all pack sizes may be marketed.

Registration holder's name and address: Ferring Pharmaceuticals Ltd., 8 Hashita St., Industrial Park, Caesarea 3088900.

Manufacturer's name and address: Ferring, Switzerland.

This leaflet was revised in August 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Pentasa prolonged release granules 1 gram: 114-57-29591
Pentasa prolonged release granules 2 grams: 138-91-31560
Pentasa prolonged release granules 4 grams: 157-47-34816