Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Pentasa Slow Release Tablets 500 mg
Pentasa Slow Release Tablets 1 gram

Composition:
Each Slow Release Tablet of 500 mg contains: 500 mg of mesalazine
Each Slow Release Tablet of 1 gram contains: 1 gram 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?

For treatment of mild to moderate ulcerative colitis and Crohn's disease.

Therapeutic group: Anti-inflammatory medicine of the salicylates class.

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 aspirin).
- have severe liver or kidney problems.

Special warnings about using this medicine

Before treatment with this medicine, tell your doctor if you:

- are allergic to sulphasalazine (risk of allergy to salicylates).
- currently or previously had liver or kidney disease.
- have a medical condition that can make you prone to bleeding.
- have an active stomach ulcer or duodenal ulcer.
- are taking medicines that may affect your kidney function, e.g. nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin.
- have a lung problem, particularly asthma.
- have kidney problems; you will need periodic check-ups by your doctor.
  Kidney stones may develop during treatment with mesalazine. Symptoms may include pain at the sides of your abdomen and blood in urine. Be sure to drink a sufficient amount of liquids during treatment with mesalazine.
- 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 a doctor immediately if you have any of the symptoms of serious skin reactions such as those described in section 4.

During treatment with this medicine

- If you suddenly start experiencing abdominal cramps, abdominal pain, fever, very severe headache and rash, **stop taking this medicine** and contact a doctor immediately.
- Avoid dehydration while taking this medicine. Dehydration may occur after prolonged vomiting and/or diarrhoea, high fever or excessive sweating. If this occurs, consult with a doctor or pharmacist as soon as possible.

Tests and follow up

During the treatment with the medicine, your doctor may refer you for blood and urine tests to verify that your kidney function is normal, especially at the beginning of treatment.

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:

- azathioprine (given after transplantations or to treat autoimmune diseases).
- 6-mercaptopurine or thioguanine (chemotherapy, used to treat leukaemia).
- certain medicines that inhibit blood clotting (medicines against thrombosis or for blood thinning, such as warfarin).

Pregnancy and breastfeeding

If you are pregnant, are planning to become pregnant, or if you are breastfeeding, consult with your doctor or pharmacist before using this medicine. There is limited experience with the use of mesalazine during pregnancy and breastfeeding. Blood disorders have been reported in newborns of mothers who have taken this medicine. The newborn may develop allergic reactions after breastfeeding, such as diarrhoea. If your newborn develops diarrhoea, stop breastfeeding.

Driving and using machines

The 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 and how you should take this medicine. The dosage and how you should take this medicine will be determined by your doctor only. The recommended dosage is usually:

– *Ulcerative colitis*

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

– *Crohn's disease*

Treatment of a severe attack and maintenance treatment: up to 4 gram per day in divided doses.
There is limited information about the efficacy of this medicine in children (from 6 to 18 years of age).

Do not exceed the recommended dose.

How to take Pentasa:

1. Do not chew or crush the tablet.
2. Swallow the tablet whole or split into halves. If you have difficulty swallowing the tablet, you may disperse it in a small amount of cold water (about 50 ml), stir and drink immediately.

If you have accidentally taken a higher dose. If you have accidentally taken an overdose, 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 forget to take the medicine. If you forgot to take this medicine at the scheduled time, take the dose as soon as you remember, as long as you have at least three hours until your next dose. Do not take a double dose to make up for the forgotten dose.

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 every time 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 Tablets may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using this medicine and contact your doctor immediately in the event of:

- 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 effects can be preceded by fever and flu-like symptoms.
- itching, skin rash, swelling of the face, lips or throat, difficulties breathing or wheeziness (signs of an allergic reaction).
- unexplained bleeding, bruising, skin rash, fever or sore throat (signs of a blood disorder).
- a change in the amount or colour of urine (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.

Additional side effects

Common side effects – side effects affecting 1-10 in 100 users:

- diarrhoea
- abdominal pain
- nausea
- vomiting
- headache
- rash
- flatulence (passing wind)

Rare side effects – side effects affecting 1-10 in 10,000 users:

- inflammation of some areas of the heart (myocarditis and pericarditis) which may cause shortness of breath and chest pain or palpitations (rapid or irregular heartbeats).
- inflammation of the pancreas (symptoms include back and/or abdominal pain).
- increased amylase (enzyme that helps digest carbohydrates).
- dizziness.
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

Very rare side effects – side effects affecting less than 1 in 10,000 users:

- anaemia and other blood disorders (decrease in the numbers of certain blood cells, which may cause unexplained bleeding, bruising, fever or sore throat)
- liver disorders (symptoms include jaundice (yellowing of the skin and/or eyes) and/or pale stool)
- 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 (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 and unexplained bleeding (e.g. nose bleeds), bruising, purple patches on the skin (including severe skin erosions and severe blistering that may affect the skin as the protective barrier of the body))
- change in urine colour
- reduced sperm count (reversible)
- severe diarrhoea and abdominal pain because of an allergic reaction of the bowel to this medicine
- allergic reactions and fever may also occasionally occur.

Side effects of unknown frequency (cannot be estimated from the available information):

- kidney stones and associated kidney pain (see also section 2).

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.

6. Additional information

In addition to the active ingredient, the tablet also contains:
microcrystalline cellulose, povidone, talc, ethylcellulose, magnesium stearate.

What the medicine looks like and contents of the pack:
Pentasa Slow Release Tablets 500 mg: the tablets are white/grey to pale brown, specked round tablets, scored and marked 'Pentasa' on one side and '500 mg' on the other side.
Pentasa Slow Release Tablets 1 gram: the tablets are white/grey to pale brown, specked oval tablets, marked 'Pentasa' on both sides.

Pentasa Slow Release Tablets 500 mg are marketed in cartons containing 10, 20, 50 or 100 tablets. Not all pack sizes may be marketed.
Pentasa Slow Release Tablets 1 gram are marketed in a carton containing 60 tablets.

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 February 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Pentasa Slow Release Tablets 500 mg: **064-73-26905**
Pentasa Slow Release Tablets 1 gr: **147-06-33401**