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 gr

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

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 aspirin.
- have severe liver or kidney problems.

Special warnings about using this medicine
Before treatment with this medicine, tell your doctor if you:
- currently or previously had liver or kidney disease.
- are taking medicines that may affect your kidney function, such as azathioprine.
- were ever allergic to a medicine containing sulphasalazine.
- 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.
- make sure that you do not become dehydrated while taking this medicine. Dehydration may occur after prolonged vomiting and/or diarrhea, high fever or heavy sweating. If this occurs, consult with your doctor or pharmacist as soon as possible.
- 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.

During treatment with this medicine
- If you experience any unexplained bleeding, bruising, skin rash, fever or sore throat – **stop taking this medicine** and refer to a doctor immediately.
- If you experience chest pain, an increased heartbeat and excessive tiredness while using this medicine – **stop taking this medicine** and refer to a doctor immediately.
- If you suddenly develop abdominal cramps, abdominal pain, fever, severe headache and rash – **stop taking this medicine** and refer to a doctor immediately.

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 (medicines that inhibit blood-clotting) (such as warfarin)
- azathioprine, 6-mercaptopurine or thioguanine

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. Babies may develop allergic reactions after breastfeeding, such as diarrhea. If your baby develops diarrhea, stop breastfeeding.

Driving and using machines
No effects on driving or using machines have been observed.

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 about the mode of treatment with a medicinal product. The dosage and mode of treatment will be determined by your doctor only. The recommended dosage is usually:
- *Ulcerative colitis*
  Treatment of a severe attack: up to 4 gr per day, which may be taken once a 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.

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 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 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 dose you missed.
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 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.
- 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 system disorder).
- a change in the color or amount of urine (signs of a kidney problem).

Additional side effects
Rare side effects – affecting 1-10 in 10,000 users:
- vomiting
- stomach pain
- nausea
- diarrhea
- headache
- inflammation of the heart or area surrounding the heart
- dizziness
- flatulence
- increased sensitivity of the skin to sunlight and ultraviolet light (photosensitivity).

Very rare side effects – affecting less than one in 10,000 users:
- elevated liver enzymes
- hair loss (reversible)
- muscle and joint pain
- allergic reactions and fever
- lupus erythematosus (an autoimmune disorder affecting the skin)
- decrease in sperm count (reversible)
- blood system disorders (such as a decrease in red blood cell count)
- tingling or numbness in the hands and feet
- allergic and fibrotic lung reactions (including breathing difficulties)
- impaired kidney function or kidney failure
- inflammation of the pancreas
- pancolitis (a type of inflammatory bowel disease – IBD) that affects the entire lining of the large intestine/colon).

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 gr: 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 gr 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 May 2021 according to MOH guidelines.

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

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