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

This medicine is dispensed with a doctor's prescription only

Pentasa Suppositories 1 gram

Composition:
Each suppository 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?

Pentasa Suppositories are indicated for the treatment of ulcerative proctitis.
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 failure.

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 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 suddenly start experiencing abdominal cramps, abdominal pain, fever, severe headache or rash, **stop taking this medicine** and contact a doctor immediately.
- Kidney stones may develop during treatment with mesalazine. Symptoms may include pain at the sides of your abdomen and blood in urine. Ensure drinking a sufficient amount of liquids during treatment with mesalazine.
- Avoid dehydration while taking this medicine. Dehydration may occur after prolonged vomiting and/or diarrhea, high fever or excessive sweating. If this occurs, consult with your doctor or pharmacist as soon as possible.

Tests and follow up
During treatment with the medicine, your doctor may refer you for blood and urine tests to ensure that your renal function is normal.

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, 6-mercaptopurine or thioguanine.
- anticoagulants (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. The baby may develop allergic reactions after breastfeeding, such as diarrhea. If your baby develops diarrhea, 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 or about the mode of treatment with a medicinal product. The dosage and mode of treatment will be determined by your doctor only. For use in adults only, not recommended for use in children. The recommended dosage for adults is usually no more than 1 suppository per day before bedtime.
The medicine is intended for rectal treatment (via the anus). To prolong the period during which the medicine remains in the body, it is recommended to insert it before bedtime.

Do not exceed the recommended dose.

Manner of using Pentasa Suppositories:
Bowel emptying is advised prior to suppository insertion.
1. Separate a single suppository by tearing the blister along the perforation.
2. Put a finger protector on the finger with which you will insert the suppository.
3. Remove the suppository from the blister before insertion by pushing the suppository through the blister.
4. To make the insertion easier, you can moisten the suppository with some water.
5. Insert the suppository gently and fully into the anus. It may be easier to do it while lying down on one side and raising the other knee.
6. Remain lying for a few minutes after insertion to help keep the suppository in place. If the suppository comes out within the first 10 minutes, a new suppository should be inserted.
7. Dispose of the empty blister and used finger protector and wash your hands.

If you have accidentally taken a higher dose. If you have accidentally used more suppositories than you should, 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 use this medicine at the scheduled time, use it as soon as you remember, but maintain an interval of at least 6 hours until your next dose.
Never take a double 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 <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 may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.
Following rectal administration, you may experience local side effects such as itching, rectal discomfort and urge for bowel emptying.

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).
- skin disorder due to an allergic reaction or infection (erythema multiforme or Stevens-Johnson syndrome). Signs include severe rash, blisters or red spots on the skin.
- unexplained bleeding, bruising, skin rash, fever or sore throat (signs of a blood system disorder).
- a change in the amount or color of urine (signs of a kidney disorder).
- chest pain, an increase in heartbeat or tiredness after exertion (signs of a heart problem).
- inflammation of the liver or liver failure. Symptoms include yellowing of the eyes and/or skin, dark urine, abdominal pain, fever, tiredness or nausea.
- inflammation of the pancreas. Symptoms include back and/or abdominal pain, fever, nausea and vomiting.
- ulcerative colitis involving the entire colon.

Additional side effects
<u>Common side effects – side effects affecting 1-10 in 100 users:</u>
- rash with or without itching

<u>Rare side effects – side effects affecting 1-10 in 10,000 users:</u>
- vomiting
- abdominal pain
- nausea
- diarrhea
- headache
- inflammation of the heart or membrane surrounding the heart
- dizziness
- flatulence
- raised level of pancreatic enzymes
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

<u>Very rare side effects – side effects affecting less than 1 in 10,000 users:</u>
- raised liver enzymes
- hair loss (reversible)
- joint and muscle pain
- allergic reactions and fever
- lupus erythematosis (an auto-immune disorder affecting the skin)
- skin rash and blisters, such as erythema multiforme or Stevens-Johnson syndrome
- decrease in sperm count (reversible)
- blood disorders (decrease in red blood cell count)
- tingling and numbness in the hands and feet
- allergic and fibrotic lung reactions (including breathing difficulties)
- decrease in kidney function or kidney failure
- inflammation of the pancreas
- pancolitis (a type of inflammatory bowel disease – IBD) that affects the entire lining of the colon.

<u>Side effects of unknown frequency (cannot be estimated from the available information):</u>
- 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 (<u>www.health.gov.il</u>) which links to an online form for reporting side effects. You can also use this link:
<u>https://sideeffects.health.gov.il</u>

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 suppositories also contains:
Povidone, macrogol 6000, magnesium stearate, talc

What the medicine looks like and contents of the pack:
Oblong, white to brown-yellowish speckled suppository. Each pack contains 28 suppositories packed in blisters of 7 suppositories and 28 finger protectors.

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: 062 73 26904.

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