

This medicine is dispensed with a doctor's prescription only

Pentasa Enema

1 gram

Composition:

Each enema 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?

For treatment of 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.

Pentasa Enema is not suitable for use in children.

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 called 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 the 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 the 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 the treatment with the medicine, your doctor may refer you for renal function tests.

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.
- certain medicines that affect 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. 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. The usual dose, unless instructed otherwise by a doctor, is one enema at night before bedtime.

Do not exceed the recommended dose.

This medicine is not intended for children, unless instructed by the doctor.

How to use Pentasa Enema:

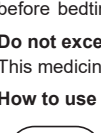


Diagram 1

1. Immediately before using the enema, remove the aluminum foil pack from the bottle and shake it well (Diagram 1).



Diagram 2

2. To break the seal, twist the nozzle clockwise one full turn (the nozzle should then be in the same direction as before turning) (Diagram 2).



Diagram 3

3. Put your hand in one of the plastic bags provided in the pack (Diagram 3).

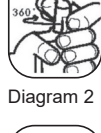


Diagram 4

4. Hold the bottle as shown in Diagram 4.



Diagram 5

5. To administer the medicine, lie on your left side with the left leg straight and the right leg bent forward for balance. Carefully insert the applicator tip into the rectum (see Diagram 5). Maintain sufficient steady hand pressure while inserting the medicine. The enema content should be emptied within maximum 30-40 seconds.

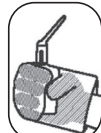


Diagram 6

6. Once the bottle is empty, withdraw the applicator from the rectum, with the bottle still compressed.

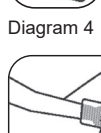


Diagram 7

7. The enema content should be retained in the bowel. Remain relaxed in the administration position for 5-10 minutes, or until the urge to pass the enema has disappeared (Diagram 7).

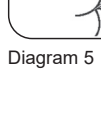


Diagram 8

8. Roll the plastic bag over the empty bottle. Discard it and wash your hands.

Please note: Pentasa Enema may cause staining of fabrics and bedding.

If you have accidentally taken a higher dose. If you have accidentally taken a higher dose 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 take this medicine at the scheduled time, use the next dose in the morning, if convenient, or next night as usually.

Do not use a double dose to compensate 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 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 (via the rectum), 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

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

- rash with or without itching

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

- 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).

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

- raised liver enzymes
- hair loss (reversible)
- joint and muscle pain
- allergic reactions and fever
- lupus erythematosus (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 (such as 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).

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, in the original package.

6. Additional information

In addition to the active ingredient, Pentasa Enema also contains:

Disodium edetate, sodium metabisulphite, sodium acetate, hydrochloric acid, purified water

What the medicine looks like and contents of the pack:

The enema is a colorless to faint yellow suspension in a plastic bottle.

Pentasa Enema pack contains 7 enema bottles and 7 polythene bags for disposal of the empty bottles.

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

Manufacturer's name and address: Ferring, Germany.

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

Registration number of the medicine in the National Drug Registry of the Ministry of Health: Pentasa Enema 137-64-2387