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**FERRING**  
 PHARMACEUTICALS

## Pentasa® Enemas 1g

**Note:** Other use or other dosages than stated below can be prescribed by your physician. In such cases the physician's prescription should be followed.

**Pharmaceutical form:**  
Enema

**Declaration of content:**

1 enema contains 1g mesalazine as the active ingredient.  
Disodium edetate dihydrate, sodium metabisulphite, sodium acetate trihydrate, hydrochloric acid and purified water are added as excipients.

**Mode of action:**

Pentasa® enemas are effective in the treatment of chronic inflammatory bowel disease.

**Manufacturer:**

Ferring A/S  
Indertøften  
DK-2720 Vanløse

**Uses:**

Chronic inflammatory bowel disease located to the colon and rectum (ulcerative proctosigmoiditis).

**Conditions where Pentasa® enemas must not be used:**

Pentasa® enemas must not be used in case of hypersensitivity to salicylates or any other component of the product, and in case of severe liver or kidney disease.

**Special warnings and precautions for use:**

In certain cases patients allergic to sulfasalazine may also suffer allergic reactions to Pentasa® (risk of allergy to salicylates).  
In case of impaired liver or kidney function further actions should be discussed with your physician. The drug is not recommended for use in patients with impaired kidney function. The kidney function should be monitored regularly, especially during the initial phase of treatment.  
Serious changes in the blood components and inflammation of the cardiac muscle and pancreas (myo- and pericarditis) are seen in rare cases. On suspicion of these adverse reactions your physician should be contacted and treatment discontinued. Symptoms can be bleeding, bruises, sore throat and fever or, in case of inflammation of the cardiac muscle and pancreas, fever and chest pain accompanied by shortness of breath.

The preparation is not recommended in children under the age of 2 years.

**Interactions with other drugs:**

None known.

**Pregnancy and lactation:**

Limited experience. Pentasa® enemas should not be used during pregnancy and lactation except on doctor's advice.

**Effects on ability to drive and use machines:**

None.

**Dosage:**

Adults: 1g (1 enema) at bedtime.

**Treatment of Overdose:**

Lack of experience. Your physician should be contacted if an overdose is suspected.

**Adverse reactions:**

Pentasa® enemas are generally well tolerated. In 1-3% of the patients diarrhoea, nausea, abdominal pain, headache, Vomiting and rash, e.g. urticaria and eczema have been observed.

Hypersensitivity reactions may occasionally occur.

Following administration of Pentasa® enemas, minor irritation such as itching, discomfort and the urge to defecate may occur.

Pain in the muscles and joints, temporary hair loss, shortness of breath, affection of the liver and kidney function, inflammation of the cardiac muscle and the pancreas as well as changes in the blood components are very rarely seen. Several of these adverse reactions can also be attributed to the disease itself. In case of any adverse reactions your physician should be contacted.

**Storage:**

Store at room temperature in unopened original package.

**Expiry date:**

See date stamp on the package.

Must not be used after the expiry date.

**Date of latest revision of the package insert:**

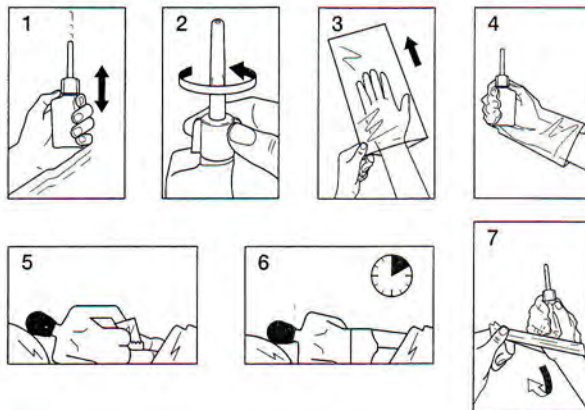
July 1998

**Instructions for use:**

Pentasa® enemas are protected by a foil bag which is removed immediately before use.

1. A visit to the toilet is recommended before administration of the enema.
2. Remove the foil bag.
3. Shake the plastic container well before use (figure 1).
4. Twist the small top section of the container all the way around (figure 2).
5. Put your hand in enclosed plastic bag and clutch the container (figure 3+4).
6. Assume a position which is suitable for inserting the enema, e.g. on your left side as shown in the drawing (figure 5).
7. Carefully insert the applicator tip into the rectum and gently press out the liquid, pressing several times, if necessary.
8. Withdraw the applicator tip while the container is still compressed.
9. Remain in the same position for 5-10 minutes or until the urge to defecate has disappeared (figure 6).
10. Roll the bag over the container before discarding it (figure 7).

**NB.** It is recommended that you protect your bedline and underwear against spillage as the enemas may discolor the fabric. If by accident you spill on the fabric put it to soak immediately.



**This is a medicine**

- Medicine is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly Follow the doctor's prescription, the method of use and the instructions of pharmacist who sold the medicine.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the prior treatment prescribed to you.
- Don't repeat the same prescription without consulting your doctor.
- Keep the medicine out of reach of children.