Please read this leaflet carefully before you start to take your medicine. It does not contain complete information about your treatment but if you have any questions or are not sure about anything ask your doctor or pharmacist (chemist). Keep this leaflet until you have finished all your treatment. You may want to read it again.

If you are helping someone else to take this medicine, please read this leaflet before you give the first dose.

About your medicine

The name of this medicine is Salofalk® Enema. The active ingredient is mesalazine and each enema contains 4.0 g of mesalazine in 60 ml of suspension. The enemas also contain sodium benzoate (E 211), potassium bisulphite (E 224), carbomer, disodium edetate, potassium acetate (E 261), xanthan gum and purified water.

Each box of Salofalk® Enema 4g/60 ml contains 7 enemas.

Holder of Product Authorisation:
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Before using Salofalk® Enema

Mesalazine belongs to a group of medicines called aminosalicylates. The action of mesalazine includes an anti-inflammatory effect in patients with chronic inflammatory bowel disease. Salofalk® Enemas are for use as an anti-inflammatory in the management of ulcerative colitis, alone or, particularly in the acute phase, with corticosteroids.

If the answer to any of the following questions is yes, tell your doctor or pharmacist.

- Are you allergic to salicylates (including aspirin)?
- Do you have an active peptic ulcer?
- Do you have a disorder of blood clotting?
- Do you have a liver or kidney disorder?
- Are you pregnant or breast feeding?
- Are you taking any other medication, including coumarin anticoagulants (to prevent blood clots), probenecid (for gout, or to prolong the effects of antibiotics), sulphinpyrazone (for gout), frusemide or spironolactone (to pass more urine), rifampicin (for an infection), non-steroidal anti-inflammatory drugs (for pain or arthritis), or glucocorticoids (e.g. for an inflammatory or allergic condition) or any other medicines which your doctor does not know about?

How to take your medicine

Adults, including the elderly:
It is important to take your medicine as directed by your doctor. The usual dose is one enema a day to be taken at bedtime although the dispensing label will tell you how many to use and how often. If it does not or you are unsure ask your doctor or pharmacist.

- This medicine should not be swallowed.
- Empty your bowels if necessary and wash your hands. Shake the bottle for 30 seconds then remove the protective cap from the applicator and hold the bottle by its upper end.

Lie down on your left side with your left leg outstretched and your right leg bent (this aids the action of the enema). Insert the applicator, which is coated with a lubricant for easy insertion into the rectum, holding the bottle pointed towards your navel.

Whilst holding the bottle tightly squeeze slowly. Remove the applicator from the rectum when the bottle is empty but maintain this position for at least 30 minutes to allow the enema to
spread throughout the lower part of the large intestine. Wash your hands again and try not to empty your bowels again until the next morning.

Children under 10 years of age: Not recommended due to lack of extended experience.
• If you forget to take your medicine continue with the next dose as instructed on the label.
• If you go into hospital or visit a dentist or another doctor tell them you are taking this medicine.

After using Salofalk® Enema

Like all medicines, Salofalk® Enema may occasionally cause side-effects in some people. Normally these effects are mild and rare but if you experience any of the following effects severely, stop using the enemas and tell your doctor as soon as possible.
• Hypersensitivity reactions such as rash, fever, chest tightness, wheezing or shortage of breath.
• Blood disorders such as increased blood levels of methaemoglobin (which reduce the normal oxygen-carrying ability of the blood) have been reported with other blood disorders which may affect the ability of the blood to clot or increase susceptibility to bruising or infection.
• Under certain conditions, some drugs with a similar structure to mesalazine may cause a butterfly-like rash on face, therefore, the possibility that this symptom might occur during treatment with Salofalk®, cannot be ruled out.
• Rarely, muscle and joint pain have been observed.
• Headache, dizziness, hair loss, pins and needles and gastrointestinal disturbances.
• Kidney, liver disturbances and in rare cases inflammation of the pancreas has been observed.
• Swelling of ankles, feet or lower leg.
• If you become dehydrated (lose too much water) which can occur with severe or prolonged vomiting and/or diarrhoea, high fever or excess sweating, contact your doctor or pharmacist for advice. Adequate fluid replacement is important in preventing kidney problems.

Note: Whilst you are taking Salofalk®, your doctor may want to check your blood count and test your kidney function from time to time, especially if you are on long-term treatment.

Benzoic acid is a mild irritant to the skin, eyes and mucus membranes. This product may be harmful to people on a low sodium or potassium diet. E 224 can cause allergic-type reactions such as rash, shortness of breath or wheezing, or swollen face in susceptible people, especially those with a history of asthma or allergy.

What to do if an overdose is taken

If you used too many enemas, contact your doctor or hospital immediately for advice. But usually your bowel cannot hold more liquid than the contents of one enema bottle. Bring a sample of the enemas with you.

Storing your medicine
• Do not use the enemas after the expiry date on the bottle and carton.
• Do not store above 25°C. Keep in the original package in order to protect from light.
• Keep all medicines out of reach and sight of children.
• If your doctor decides to stop treatment, return any left over enemas to the pharmacist. Only keep them if the doctor tells you to.
• If the enemas look to be deteriorating in any way, do not use but return them to the pharmacist.

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REMEMBER: This medicine is yours. Never give it to others. It may not be suitable for them even if their symptoms are the same as yours.