

Package leaflet: information for the user

Salofalk Enema 2g Mesalazine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet:

1. What Salofalk enemas are and what they are used for
2. What you need to know before you use Salofalk enemas
3. How to use Salofalk enemas
4. Possible side effects
5. How to store Salofalk enemas
6. Contents of the pack and other information

1. What Salofalk Enemas 2g are and what they are used for

Salofalk enemas contain the active substance mesalazine, an anti-inflammatory agent used to treat inflammatory bowel disease.

Salofalk enemas are used for:

- the treatment of mild episodes of an inflammatory disease in parts of the colon and the rectum (back passage) known by doctors as ulcerative colitis or ulcerative proctitis.

2. What you need to know before you use Salofalk Enema 2g

Do not use Salofalk enemas

- If you are allergic to mesalazine, salicylic acid, salicylates such as aspirin or any of the other ingredients of this medicine (listed in section 6).
- If you have a serious liver or kidney disease.

Warnings and precautions

Talk to your doctor or pharmacist before using Salofalk enemas:

- If you have a history of problems with your lungs, particularly if you suffer from **bronchial asthma**.
- If you have a history of allergy to sulphasalazine, a substance related to mesalazine.
- If you suffer with problems of your **liver**.
- If you suffer with problems of your **kidney**.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Further precautions

During treatment your doctor may want to keep you under close medical supervision, and you may need to have regular blood and urine tests.

Kidney stones may develop with use of mesalazine. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with mesalazine.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis have been reported in association with mesalazine treatment. Stop using mesalazine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and Salofalk Enema 2g

Tell your doctor if you take or use any of the medicines mentioned below as the effects of these medicines may change (interactions):

- Azathioprine, 6-mercaptopurine or thioguanine (medicines used to treat immune disorders).
- Certain agents that inhibit blood clotting (medicines for thrombosis or to thin your blood, e.g., warfarin)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. It may still be alright for you to use Salofalk enemas and your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

You should only use Salofalk enemas during pregnancy if your doctor tells you to.

You should also only use Salofalk enemas during breast-feeding if your doctor tells you to, as this medicine may pass into breast milk.

Driving and using machines

There are no effects on the ability to drive and use machines.

Salofalk Enema 2g contains potassium metabisulphite and sodium benzoate

Potassium metabisulphite may rarely cause severe hypersensitivity reactions and bronchospasm.

This medicinal product contains 60 mg sodium benzoate in each Salofalk Enema 2g. Sodium benzoate may cause local irritation.

3. How to use Salofalk Enema 2g

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration

This medicine may only be used rectally, so it has to be inserted through the anus. Do NOT take by mouth.

Dosage

Adults and elderly:

The recommended dose is one enema once a day, at bedtime.

For the best results empty your bowels before using the enema.

- Shake the bottle well for at least 30 seconds before use to ensure thorough mixing.
- Remove the protective cap. Hold the container upright to avoid spillage.
- Lie on your left side with your left leg stretched out and your right knee bent for balance. If this is not convenient, then lie on your right side with your right leg stretched out and your left leg bent for balance to apply the enema but turn to your left side after application.
- Insert the lubricated applicator deep into your rectum. Keep the bottle pointed towards your navel.
- Tip the bottle slightly downwards and then squeeze it slowly and evenly.
- Once the bottle is empty, slowly remove the applicator.
- Lie on your left side for at least 30 minutes to enable the medicine to spread evenly through the bowel. Try to retain the enema all night.

Use in children

There is little experience and only limited documentation for an effect in children.

Duration of treatment

Your doctor will decide how long you need to continue the treatment with this medicine. This will depend on your condition.

To obtain the maximum benefit from this medicine, you should use Salofalk enemas regularly and consistently, as directed.

If you think your Salofalk enemas are too strong or too weak, talk to your doctor.

If you use more Salofalk enemas than you should

Contact a doctor if you are in doubt, so he or she can decide what to do.

If you use too many enemas on one occasion, just use your next dose as prescribed. Do not use a smaller amount.

If you forget to use Salofalk enemas

Do not use a larger than normal dose of Salofalk enema next time, but continue treatment at the prescribed dosage.

If you stop using Salofalk enemas

Do not stop using this product until you have talked to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Salofalk enemas can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are very rare. If you get any of the following symptoms after using this medicine, you should contact your doctor immediately:

- **Allergic skin rash**
- **Fever**

– **Breathing difficulties**

If you experience a marked reduction of your general health, especially if accompanied by fever, and/or a sore throat and mouth, stop using the enemas and contact your doctor immediately. These symptoms can, very rarely, be due to a fall in the number of white cells in your blood (a condition called agranulocytosis) which may make you more prone to developing a serious infection. A blood test can confirm whether your symptoms are due to an effect of this medicine on your blood.

Stop using mesalazine and seek medical attention immediately if you notice any of the following symptoms:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms.

The following side effects have also been reported by patients using mesalazine:

Rare side effects (that affect less than 1 in 1,000 patients):

- Abdominal pain, diarrhoea, wind (flatulence), nausea and vomiting, constipation
- Headache, dizziness
- Chest pain, breathlessness or swollen limbs because of an effect on your heart
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)

Very rare side effects (that affect less than 1 in 10,000 patients):

- Changes in kidney function, sometimes with swollen limbs or flank pain
- Severe abdominal pain because of acute inflammation of the pancreas
- Fever, sore throat or malaise because of blood count changes
- Shortness of breath, cough, wheezing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions
- Severe diarrhoea and abdominal pain because of an allergic reaction to this medicine within the bowel
- Skin rash or inflammation
- Muscle and joint pain
- Jaundice or abdominal pain because of liver and bile flow disorders
- Hair loss and the development of baldness
- Numbness and tingling in the hands and feet (peripheral neuropathy)
- Reversible decrease in semen production

Not known (frequency cannot be estimated from the available data):

- Kidney stones and associated kidney pain (see also section 2)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Salofalk Enema 2g

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and on the carton. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.
Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Salofalk enemas contain

The active substance is mesalazine and one enema contains 2g mesalazine.

The other ingredients are

Carbomer 35 000, disodium edetate, potassium acetate (E261), potassium metabisulphite (E224), purified water, sodium benzoate (E211), xanthan gum (E415).

What Salofalk enemas look like and contents of the pack

Salofalk enemas are in a low-density, concertina shaped, polythene bottle with a low-density polythene application nozzle.

Salofalk enemas are available in packs of 7.

Marketing Authorisation Holder

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