

Package leaflet: information for the user

Salofalk® 4g/60ml Enema Mesalazine (5-aminosalicylic acid)

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 4g/60ml Enema is and what it is used for
2. What you need to know before you use Salofalk 4g/60ml Enema
3. How to use Salofalk 4g/60ml Enema
4. Possible side effects
5. How to store Salofalk 4g/60ml Enema
6. Contents of the pack and other information

1. What Salofalk 4g/60ml Enemas are and what they are used for

Salofalk 4g/60ml Enemas contain the active substance mesalazine, an anti-inflammatory agent used to treat inflammatory bowel disease.

Salofalk 4g/60ml Enemas are used for the treatment of:

Inflammation of the large intestine (colon) and rectum (back passage) known by doctors as ulcerative colitis. It may be used alone or, particularly in the acute phase, with corticosteroids.

2. What you need to know before you use Salofalk 4g/60ml Enemas

Do not use Salofalk 4g/60ml Enema:

- If you are allergic to salicylic acid, to salicylates such as acetylsalicylic acid (e.g., aspirin) or to any of the other ingredients of Salofalk 4g/60ml Enemas (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 4g/60ml 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.

Mesalazine may produce red-brown urine discoloration after contact with sodium hypochlorite bleach in the toilet water. It concerns a chemical reaction between mesalazine and bleach and is harmless.

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 drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) 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.

If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears contact your doctor immediately.

Other medicines and Salofalk 4g/60ml Enema

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

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

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 all right for you to use Salofalk 4g/60ml Enema 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 4g/60ml Enema during pregnancy if your doctor tells you to.

You should only use Salofalk 4g/60ml Enema 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 4g/60ml Enema 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 4g/60ml Enema. Sodium benzoate may cause local irritation.

3. How to use Salofalk 4g/60ml Enema

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. It is not intended to be taken by mouth. Do not swallow. Salofalk 4g/60ml Enema should be administered preferably at bedtime.

- Empty your bowels if necessary and wash your hands.
- Shake the bottle for at least 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.

Dosage:

Adults and the elderly

Unless otherwise prescribed by your doctor, the recommended dose for the treatment of acute episodes of ulcerative colitis is one enema a day to be used at bedtime.

Use in children and adolescents

There is little experience and information about the effect of this medicine when used in children.

Duration of treatment

How long you will use the medicine depends upon your condition. Your doctor will decide how long you are to continue the medication.

You should follow the treatment with Salofalk 4g/60ml Enema regularly and consistently, because this is the only way to achieve the desired therapeutic effect.

If you think that the effect of Salofalk 4g/60ml Enema is too strong or too weak, talk to your doctor.

If you use more Salofalk 4g/60ml Enema than you should

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

If you use too much Salofalk 4g/60ml Enema on one occasion, just use your next dose as prescribed.

Do not use a smaller amount.

If you forget to use Salofalk 4g/60ml Enema

Do not use a double dose of Salofalk 4g/60ml Enema next time, but continue treatment at the prescribed dosage.

If you stop using Salofalk 4g/60ml Enema

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, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following symptoms after taking this medicine, you should contact your doctor and stop using Salofalk enemas immediately:

- **General allergic reactions** such as skin rash, fever, joint pain and/or breathing difficulties or a general inflammation of your large bowel (causing severe diarrhoea and abdominal pain). These reactions are very rare.
- A marked reduction of your general health, especially if accompanied by fever, and/or a sore throat and mouth. These symptoms can, very rarely, be due to a fall in the number of white cells in your blood, which may make you more prone to developing a serious infection (**agranulocytosis**). Other cells of the blood may also be affected (e.g., platelets or red cells causing **aplastic anaemia or thrombocytopenia**) and cause symptoms which may include unexplained bleeding, purple spots or patches under your skin, anaemia (feeling tired, weak and looking pale, especially on lips and nails). A blood test can confirm whether your symptoms are due to an effect of this medicine on your blood. These reactions are very rare.
- **Serious skin rashes** with 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, widespread rash, fever and enlarged lymph nodes. These can be preceded by fever and flu-like symptoms. These reactions occur in an unknown number of patients (frequency not known).

- Shortness of breath, chest pain or irregular heartbeat, or swollen limbs which may be indicative of **cardiac hypersensitivity reactions**. These reactions are rare.
- **Problems with your kidney** function (can occur very rarely), e.g., a change in the colour or amount of urine produced and swollen limbs or a sudden flank pain (caused by a kidney stone) (occur in an unknown number of patients (frequency not known)).
- **Strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears**. These could be symptoms of increased pressure within your skull (idiopathic intracranial hypertension) (frequency not known [cannot be estimated from the available data]).

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

Common: may affect less than 1 in 10 people

- Rash, itching

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

- Abdominal pain, diarrhoea, wind (flatulence), nausea vomiting, constipation
- Headache, dizziness
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)

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

- Severe abdominal pain because of acute inflammation of the pancreas
- Shortness of breath, cough, wheezing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions
- 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

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 as follows:

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Salofalk 4g/60ml Enema

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the container on the bottom of 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.

6. Contents of the pack and other information

What Salofalk 4g/60ml Enemas contain

The active substance is mesalazine and one enema contains 4g of mesalazine.

The other ingredients are

Sodium benzoate (E 211), potassium metabisulphite (E 224), carbomer, disodium edetate, potassium acetate (E 261), xanthan gum and purified water.

What Salofalk 4g/60ml Enemas look like and contents of the pack

The enema is a creamy coloured suspension. It is contained in a white, opaque plastic bottle with a lubricated applicator.

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

Marketing Authorisation Holder and Manufacturer

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