

PACKAGE LEAFLET: INFORMATION FOR THE USERS

Asacol Foam Enema

(mesalazine)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Asacol Foam Enema is and what it is used for
2. Before you use Asacol Foam Enema
3. How to use Asacol Foam Enema
4. Possible side effects
5. How to store Asacol Foam Enema
6. Further information

1. WHAT ASACOL FOAM ENEMA IS AND WHAT IT IS USED FOR

Asacol Foam Enema contains the active substance mesalazine (also known as 5-aminosalicylic acid) which is an anti-inflammatory drug used in the treatment of **Ulcerative colitis**.

Ulcerative colitis is a disease of the large bowel (colon) and back passage (rectum) in which the lining of the bowel becomes inflamed (red and swollen). Symptoms can include rectal bleeding, frequent diarrhoea and abdominal pain. The enema acts locally in the lower part of the colon to reduce the inflammation.

2. BEFORE YOU USE ASACOL FOAM ENEMA

Do not use Asacol Foam Enema if you:

- are **allergic** (hypersensitivity) to any of the ingredients in the product (see Section 6 on 'What Asacol Foam Enema contains')
- are allergic to **aspirin** or any other salicylate
- had **kidney** problems or **blood** abnormalities while taking other medicines such as **sulphasalazine**
- have confirmed severe **kidney** impairment.

Do not use the foam in **children** under 2 years of age.

Take special care with Asacol Foam Enema

- Asacol should be used with extreme caution in patients with confirmed mild to moderate kidney impairment
- Asacol should be used with caution in the elderly.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription.

Use of **non-steroidal anti-inflammatory drugs** (NSAIDs such as ibuprofen, aspirin, Cox-II inhibitors) and **azathioprine** in particular may increase the risk of kidney reactions.

Pregnancy and breast-feeding

Women who are pregnant or breast-feeding should not use Asacol Foam Enema unless advised otherwise by their doctor. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Asacol Foam Enema is not expected to affect your ability to drive or operate machinery.

3. HOW TO USE ASACOL FOAM ENEMA

Please read these instructions carefully, even if you have used Asacol Foam Enema before, as these instructions have recently changed.

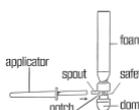
Asacol Foam Enema should not be swallowed.

Please use the product with care as it may cause staining to clothing and household articles.

DOSE FOR ADULTS AND THE ELDERLY: Please read the pharmacist's label carefully as your doctor will have instructed you whether to use one or two doses each day.

This medicine should be delivered to the back passage (rectum) as described below:

1. Before using the enema for the first time, thoroughly mix the contents by **shaking the can vigorously for 15 seconds**. Rest for about 30 seconds, and then **shake the can vigorously for another 15 seconds**.
2. Also, before using the enema for the first time, remove the safety tag from under the dome.
3. Push the plastic applicator firmly onto the spout of the can and align the notch beneath the dome with the spout.
4. Hold the can in the palm of one hand with the dome pointing downwards. This product must only be dispensed when the can is upside down, with the dome nearest the ground (if the can is not upside down, the foam will not come out properly).
5. You may find the easiest way to use the enema is to raise one foot onto a firm surface such as a stool or chair, and insert the applicator into the rectum as far as is comfortable. You can apply a lubricating jelly to the tip of the applicator for comfort if you wish.
6. To administer one dose, fully push the dome down once and release it. **The foam will not come out of the can until you release the dome**. To administer a second dose, press and release the dome again. Wait for 15 seconds before withdrawing the applicator. **Note, the can will only work properly when held with the dome pointing downwards**.
7. Remove the applicator and dispose of it in one of the plastic bags provided. **Do not** flush it down the toilet. Wash your hands.
8. Before using the enema again, mix the contents of the can by shaking vigorously for 5 seconds only, before continuing to use the enema as instructed above.



DO NOT use Asacol Foam Enema more than twice in 12 hours.

Do not use this medicine in children under 2 years of age.

Keep using the foam until your prescribed course is finished. Your symptoms may come back if you stop treatment too early. Your doctor will normally recommend that you take treatment for between 4 and 6 weeks.

If you use more Asacol Foam Enema than you should

Do not exceed the recommended dose. You should only use as much enema as your doctor has instructed on the pharmacist's label. If you use too much, tell your doctor immediately or go to your nearest Accident & Emergency Department (take the foam enema pack with you if possible).

If you forget to use Asacol Foam Enema

If you forget to use your enema at the required time, take the dose as soon as you remember and continue using the foam as before. Do not use Asacol Foam Enema more than twice in 12 hours.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Asacol Foam Enema can cause side effects, although not everybody gets them.

Allergic reactions to the enema can occur. Tell your doctor if you get a rash (with or without itching), any shortness of breath, palpitations (rapid heart beat) or chest pain. These effects will usually disappear when you stop using the medicine.

Tell your doctor immediately if you experience any of the following symptoms:

- fever, sore throat, mouth or lip ulcers, spots underneath your skin anywhere on your body, including the genital and anal regions, become very pale, swollen ankles or have unusual bleeding (e.g. unexpected nosebleeds or bleeding gums)
- skin rash with flaking, boils or sore lips or mouth
- bruising more easily or suspect blood abnormalities
- problems with kidney function.

Common side effects:

- diarrhoea
- abdominal pain
- nausea (feeling sick)
- headache.

Rare side effects:

- problems with heart, lung, liver or kidney function
- inflammation of the pancreas
- blood abnormalities
- numbness and tingling of the fingers and toes due to damaged nerves
- hair loss
- skin rash
- local irritation at site of application.

Very rare side effects:

- worsening of symptoms of colitis
- Erythema multiforme and Stevens-Johnson syndrome (skin and mucous membrane disease).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5. HOW TO STORE ASACOL FOAM ENEMA

Keep out of the reach and sight of children.

Store Asacol Foam Enema below 30°C (86°F).

Keep the medicine away from flames or sparks (including cigarettes) and protect from direct sunlight. Do not pierce or burn the product, even when it is empty.

Do not use the enema after the expiry date stated on the pack after 'Exp'. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Asacol Foam Enema contains

The **active** substance is mesalazine (5-aminosalicylic acid). Each metered dose contains 1g of mesalazine. The **other** ingredients are sorbitan oleate, polysorbate 20, emulsifying wax, colloidal anhydrous silica, sodium metabisulphite (E223), disodium edetate, methylparahydroxybenzoate (E218), propylparahydroxybenzoate (E216), disodium phosphate dodecahydrate, sodium acid phosphate, glycerol (E422), macrogol 300, purified water, propane, iso-butane, n-butane.

What Asacol Foam Enema looks like and contents of the pack

Asacol Foam Enema is a white foam. It is supplied in an aerosol can containing 14 metered doses with 14 disposable applicators and 14 disposable plastic bags.

Marketing Authorisation Holder

Allergan Pharmaceuticals International Limited, Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland **Manufacturer**
Pharmasol Limited, North Way, Walworth Industrial Estate, Andover, Hampshire, SP10 5AZ, United Kingdom.

Getting more advice about ulcerative colitis

In addition to advice and information available from your doctor and pharmacist, you may wish to contact the National Association for Colitis and Crohn's Disease which offers information, advice and local support groups:

National Association for Colitis and Crohn's Disease

4 Beaumont House, Sutton Road, St. Albans, Hertfordshire, AL1 5HH

Large print, braille, audio format leaflet

To obtain this leaflet in large print, braille or audio format, please call the following free-phone number: 0800 198 5000.

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