

# Asacol 250mg and 500mg suppositories

## (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 Suppositories are and what they are used for
2. Before you use Asacol Suppositories
3. How to use Asacol Suppositories
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### 1. WHAT ASACOL SUPPOSITORIES ARE AND WHAT THEY ARE USED FOR

Asacol Suppositories contain the active substance mesalazine (also known as 5-aminosalicylic acid) which is an anti-inflammatory drug used in the treatment of **Ulcerative colitis** – 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 suppositories act locally in the rectum to reduce inflammation and can also prevent further episodes (flares) of ulcerative colitis. They are particularly useful when symptoms of ulcerative colitis affect the rectum.

### 2. BEFORE YOU USE ASACOL SUPPOSITORIES

**Do not use Asacol suppositories** if you:

- are allergic (hypersensitive) to any of the ingredients in the product (see Section 6 on “What Asacol Suppositories contain”).
- 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 give the suppositories to **children** under 2 years of age.

### Take special care with Asacol Suppositories

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

### 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 Suppositories unless advised otherwise by their doctor. Ask your doctor or pharmacist for advice before taking any medicine.

### Driving and using machines

Asacol Suppositories are not expected to affect your ability to drive or operate machinery.

### 3. HOW TO USE ASACOL SUPPOSITORIES

Asacol Suppositories are available in two strengths and contain either 250mg or 500mg of mesalazine. Your doctor will have prescribed one strength of suppositories for you.

**Dose for adults and the elderly:** Please read the pharmacist's label carefully as your doctor will have instructed you to use either

- three to six 250mg suppositories a day with the last dose at bedtime, or
- one to three 500mg suppositories a day with the last dose at bedtime.

DO NOT use more than six 250mg suppositories a day or more than three 500mg suppositories a day.

A suppository should be inserted into the back passage (rectum) as described below:

1. Empty your bowels, if necessary, and wash your hands.
2. Remove the plastic wrapping from the suppository.
3. Squat or bend forward.
4. Gently, but firmly, place the suppository (pointed end first) into your back passage. If necessary, grease the tip of the suppository with petroleum jelly.
5. Wash your hands again
6. Try not to empty your bowels for at least an hour after inserting the suppository.

### Asacol Suppositories are not recommended for use in children.

DO NOT swallow this medicine. If you have accidentally swallowed a suppository, drink plenty of water and tell your doctor immediately or visit your nearest Accident & Emergency Department (take the suppository pack with you if possible).

Keep using the suppositories until your prescribed course is finished. Your symptoms may come back if you stop treatment too early.

### If you use more Asacol Suppositories than you should

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

### If you forget to use Asacol Suppositories

If you forget to insert a suppository at the required time, use them as soon as you remember and continue using your suppositories as before. DO NOT use more than two suppositories in one hour.

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 Suppositories can cause side effects, although not everybody gets them.

**Allergic reactions to the suppositories 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 nerve endings
- hair loss
- skin rash
- local irritation at the 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](http://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 SUPPOSITORIES**

Keep out of the reach and sight of children.

Store Asacol Suppositories in their original pack below 25°C (77°F) and protect from light.

Do not use the medicine after the expiry date which is 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 Suppositories contain**

The **active** substance is mesalazine (also known as 5-aminosalicylic acid). Each suppository contains 250mg or 500mg mesalazine.

The **other** ingredient is Witepsol W45 (hard fat).

**What Asacol Suppositories look like and contents of the pack**

The suppositories are opaque beige coloured, cone-shaped and meltable, available in packs of 20 x 250mg and 10 x 500mg strengths.

**Marketing Authorisation Holder and Manufacturer**

Allergan Pharmaceuticals International Limited, Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland

**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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