

PACKAGE LEAFLET

Package leaflet: Information for the patient
Asacolone 1000 mg Suppositories
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

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2. What you need to know before you use Asacolone 1000 mg Suppositories
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1. What Asacolone 1000 mg Suppositories are and what they are used for

Asacolone 1000 mg Suppositories contain the active substance mesalazine, an anti-inflammatory agent used to treat inflammatory bowel disease.

Asacolone 1000 mg Suppositories are used for the treatment of acute mild to moderate ulcerative colitis limited to the rectum (ulcerative proctitis).

2. What you need to know before you use Asacolone 1000 mg Suppositories

Do not use Asacolone 1000 mg Suppositories

- if you are allergic to salicylic acid, to salicylates such as acetylsalicylic acid (aspirin) or 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 before using Asacolone 1000 mg Suppositories

- 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 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.

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.

Other medicines and Asacolone 1000 mg Suppositories

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. It may still be all right for you to use Asacolone 1000 mg Suppositories 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 Asacolone 1000 mg Suppositories during pregnancy, if your doctor tells you to.

You should also only use Asacolone 1000 mg Suppositories during breast-feeding, if your doctor tells you to, as this medicine may pass into breast milk.

Driving and using machines

Asacolone 1000 mg Suppositories are not expected to affect your ability to drive or operate machines.

3. How to use Asacolone 1000 mg Suppositories

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 older people

To treat acute phase of ulcerative proctitis the recommended dose is one Asacolone 1000 mg suppository once a day, at bedtime.

To prevent recurrence of ulcerative proctitis the recommended dose is one Asacolone 1000 mg suppository once a day, at bedtime.

The dose should be adjusted by your doctor as per your condition.

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 Asacolon 1000 mg Suppositories regularly and consistently, as directed.

If you think your Asacolon 1000 mg Suppositories are too strong or too weak, talk to your doctor.

If you use more Asacolon 1000 mg Suppositories 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 Asacolon 1000 mg Suppositories on one occasion, just take your next dose as prescribed.

Do not use a smaller amount.

If you forget to use Asacolon 1000 mg Suppositories

If you forget to use this medicine, use it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Then use the next dose at its usual time. Do not use a double dose to make up for a forgotten dose.

If you stop using Asacolon 1000 mg Suppositories

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

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

4. Possible side effects

Like all medicines, this medicine 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**
- 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 serious skin rashes can be preceded by fever and flu-like symptoms.
- **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 these suppositories 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.

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

Rare side effects (may affect up to 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 (may affect up to 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 or 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 HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2; Tel: +353 1 6764971, Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store Asacolon 1000 mg Suppositories

Keep this medicine out of the sight and reach of children.

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

Do not store above 30°C.

Store in the original container in order to protect contents 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 Asacolon 1000 mg Suppositories contains

- The active substance is mesalazine and one suppository of Asacolon 1000 mg Suppositories contains 1000 mg mesalazine.
- The other ingredient is hard fat.

What Asacolon 1000 mg Suppositories look like and contents of the pack

Asacolon 1000 mg Suppositories are light beige coloured, torpedo-shaped suppositories.

Asacolon 1000 mg Suppositories are available in packs of 10, 20, 30, 60 and 90 suppositories.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Tillotts Pharma GmbH
 Warmbacher Strasse 80
 79618 Rheinfelden
 Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic, Denmark, Finland, Germany, Island, Norway, Spain, Sweden: Asacol
 Austria, Estonia, Latvia, Lithuania: Yaldigo
 Ireland: Asacolon

France: Fivasa
Greece, The Netherlands: Kiudro

This leaflet was last revised in 01/2023.

Other sources of information

Detailed information on this medicine is available on the website of HPRA, www.hpra.ie

In addition you may wish to contact the National Association for Colitis and Crohn's Disease which offers information, advice and local support groups.

Irish Society for Colitis and Crohn's Disease
Carmichael House, North Brunswick Street, DUBLIN 7