

PACKAGE LEAFLET: INFORMATION FOR THE USER

Asacol[®] 500 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:

1. What Asacol[®] is and what it is used for
2. What you need to know before you use Asacol[®]
3. How to use Asacol[®]
4. Possible side effects
5. How to store Asacol[®]
6. Contents of the pack and other information

1. What Asacol[®] is and what it is used for

Asacol[®] contains the active ingredient mesalazine, an anti-inflammatory medicine used to treat proctitis, procto-sigmoiditis and ulcerative colitis. These are diseases of the large bowel (colon) and the back passage (rectum), in which the bowel lining becomes inflamed (red and swollen). Asacol[®] Suppositories act locally on the lining (mucosa) of the lower part of the colon and rectum to reduce this inflammation. Asacol[®] Suppositories are particularly useful when the symptoms of ulcerative colitis affect the rectum.

2. What you need to know before you use Asacol[®]

Do not use Asacol[®]

- If you are allergic to mesalazine or any of the other ingredients of this medication, listed in section 6.
 - If you are allergic to salicylates (e.g. Aspirin).
 - If you have severe kidney impairment.
 - If you have severe liver impairment.
- Asacol[®] 500 mg Suppositories contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product

Do not use Asacolon in children under 2 years of age.

Warnings and precautions

Talk to your doctor before using Asacolon if you have any medical conditions or illnesses, particularly if you have:

- any lung problems, e. g. asthma.
- liver disease.
- kidney disease.
- suffered an allergy to sulphasalazine in the past.
- ever had allergic reactions of your heart such as inflammation of the heart muscle or heart sac. If you have had previous suspected mesalazine-induced allergic reactions of your heart, then Asacolon must not be taken. Asacolon can be taken with care if you have had a previous allergic reaction of the heart not caused by mesalazine.
- Blood dyscrasia, a condition in which different constituents of blood, such as white blood or red blood cells and platelets, are either high or too low in counts.
- ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Serious skin reactions including Drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), 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 have ulcer of the stomach or intestine, you may take Asacolon with care.

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

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.

Test for your liver, kidney and blood

As a guideline, follow-up tests are recommended 14 days after commencement of treatment and then every 4 weeks for the following 12 weeks. If the findings are normal, follow-up tests should be carried out every three months. If additional signs appear, these tests should be performed immediately.

Children and adolescents

There is little experience and only limited documentation for an effect of Asacolon in children. Do not use Asacolon in children under 2 years of age.

Other medicines and Asacol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, such as:

- Medicines affecting the immune system (e.g. azathioprine, or 6-mercaptopurine, or thioguanine)
- Medicines that prevent the formation of blood clots (anticoagulants, e.g. warfarin).

Asacolon with food, drink and alcohol

The consumption of food, drink, and alcohol does not interfere with the use of Asacolon.

Pregnancy, breast-feeding and fertility

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.

Driving and using machines

Asacolon has no or negligible influence on the ability to drive and use machines. However, if you are affected in anyway do not drive or operate machinery.

3. How to use Asacolon

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

Instruction for proper use

Do not swallow your suppositories. They should be inserted into the back passage (rectum).

The information below tells you how to insert a suppository:

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 - flat end first - into the back passage. If necessary, grease the tip of the suppository with a lubricant.
5. Wash your hands again.
6. Try not to empty your bowels for at least an hour after inserting the suppository.

The recommended dose is:

Adults (including older people)

One to three suppositories a day in divided doses. Your doctor will establish an appropriate dose for you individually according to your condition. The maximum daily dose is three suppositories in divided doses. The pharmacist's label on your suppository pack will tell you how many suppositories your doctor would like you to use. Please read the label carefully.

Use in children and adolescents:

There is not enough experience and insufficient documentation demonstrating the effect in children and adolescents.

If you use more Asacolon than you should

If you use more Asacolon than you should or this medicine was consumed by a child, speak immediately with your doctor.

If you have swallowed an 'Asacolon' 500 mg Suppository by mistake

Drink plenty of water and tell your doctor or hospital casualty department straight away. Take your suppository pack with you.

If you forget to use Asacolon

If you forget to use a dose at the right time, just use the next dose as normal.

Do not use a double dose to make up for a forgotten dose.

If you stop using Asacolon

Do not stop using Asacolon without talking to your doctor first even if you feel better. 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. Organ specific side effects affecting the heart, lungs, liver, kidneys, pancreas, skin and subcutaneous tissue have been reported.

Stop using Asacolon immediately and seek urgent medical advice

If you develop unexplained bruising (without injury), bleeding under your skin, purple spots or patches under your skin, anaemia (feeling tired, weak and looking pale, especially on lips, nails and inside of eyelids), fever (high temperature), sore throat or unusual bleeding (e.g. nose bleeds), 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.

The following side effects have been reported at the approximate frequencies shown:

Rare (may affect up to 1 in 1,000 people):

- headache
- dizziness
- inflammation of the heart with signs like chest pains or palpitations
- diarrhoea, stomach pain, wind (flatulence), feeling of unease and discomfort in the stomach with an urge to vomit and vomiting
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

Very rare (may affect up to 1 in 10,000 people):

- severe reduction in blood cells which can cause weakness, bruising or make infections more likely, low blood cell counts; reduction in blood platelets which increases the risk of bleeding
- allergic reactions such as rash or skin eruption
- fever that occurs while taking the medicine and which disappears when the medicine is stopped (drug fever)
- immune system disease that can involve organs and joints
- ulcerative colitis involving the entire large intestine
- abnormal or damaged nerves giving a sensation of numbness and tingling
- lung disease (scarring of lung tissue, allergic reaction) resulting in difficulty in breathing, cough, wheezing and collection of fluid in the lungs
- inflamed pancreas (associated with pain in upper abdomen and back and feeling sick)

- abnormal liver function tests, hepatitis (inflammation of the liver giving rise to flu-like symptoms and jaundice)
- hair loss
- muscle or joint pain
- kidney problems (such as inflammation and scarring of the kidney), reduced kidney function
- reversible decrease in sperm production

Not known (cannot be estimated from the available data)

- inflammation of the membranes of the pleural cavity surrounding the lungs (pleurisy)
- kidney stones and associated kidney pain (see also section 2)
- intolerance to mesalazine sometimes with worsening symptoms of underlying disease
- local reaction

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – 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

Keep this medicine out of the sight and reach of children. Do not store above 25 °C, refrigerate or freeze. Store in a dry place protected from direct heat. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the blister and carton after “Expiry date:” or “Exp” in the form of MM.YYYY (month - year). The expiry date refers to the last day of that month.

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 protect the environment.

6. Contents of the pack and other information

What Asacolon contains

- The active substance is mesalazine.
- Each suppository contains 500 mg mesalazine.
- The other ingredients are:
hard fat
lecithin, derived from soya oil.

What Asacolon looks like and contents of the pack

Asacolon 500 mg Suppositories are torpedo-shaped suppositories with a light grey-brown

colour.

Asacolone 500 mg Suppositories come in PVC/polyethylene laminate foil strips of 5 suppositories packed in an outer cardboard carton containing 20 suppositories.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is:

Tillotts Pharma GmbH
Warmbacher Str. 80
79618 Rheinfelden
Germany

The manufacturers are:

Haupt Pharma Wülfing GmbH
Bethelner Landstrasse 18
31028 Gronau/Leine
Germany

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

'Asacolone' is a registered trade mark.

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