

This medicine is dispensed with a doctor's prescription only

Asacol

400 mg

Enteric-coated tablets

Active ingredient:

mesalazine (5-aminosalicylic acid) 400 mg/tablet

Asacol

800 mg

Enteric-coated tablets

Active ingredient:

mesalazine (5-aminosalicylic acid) 800 mg/tablet

Inactive ingredients and allergens: see section 2 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

This medicine is intended for treating ulcerative colitis (acute exacerbation of colitis) and Crohn's disease (acute episodes) and for preventing recurrent episodes of ulcerative colitis.

Therapeutic group: aminosalicylates.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (listed in section 6 'Additional information')
- You are sensitive (allergic) to salicylates such as aspirin
- You have severe kidney problems
- You have severe liver problems
- Children under two years old

Special warnings about using this medicine

Before starting treatment with Asacol, tell the doctor if:

- you have ever had any problems with your liver or kidneys, particularly if you are elderly
- you have any problems with the lungs, such as asthma
- you suffered an allergy to sulfasalazine in the past
- you have ever had allergic reactions of your heart such as inflammation of the heart muscle or heart sac. If you have had previous allergic reactions of your heart that may have been caused by mesalazine, do not take Asacol. You can take Asacol under supervision if you have had a previous allergic reaction of the heart that was not caused by mesalazine.
- you have 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), 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.

- you have an ulcer of the stomach or intestine, you may take Asacol under supervision.

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

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.

Children and adolescents: The safety and efficacy of Asacol tablets in children have not been fully established.

Tests and follow-up

Before and during use of this medicine, your doctor may want to monitor you from time to time, to check that your liver, kidneys, blood and lungs are all right.

There have been a few reports of intact tablets in the stool. What appear to be intact tablets may sometimes be the remains of the tablet coating. If you often observe tablets or tablet coating in the stool, you should consult your doctor.

Other medicines and Asacol

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly tell your doctor or pharmacist if you are taking:

- medicines that affect the immune system such as azathioprine, 6-mercaptopurine, or thioguanine
- medicines that prevent the formation of blood clots (anticoagulants such as warfarin)

Using this medicine and food

Take the medicine before meals. You may eat and drink normally (including alcohol), during treatment with this medicine.

Pregnancy, breastfeeding, and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines:

This medicine is not expected to affect your ability to drive or operate machines.

However, if you are affected in anyway, do not drive or operate machines.

Important information about some of this medicine's ingredients

This medicine contains lactose (milk sugar).

Patients who are intolerant to lactose should note that this medicine contains a small amount of lactose. If your doctor has told you that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, i.e. is essentially "sodium-free".

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The usually recommended dosage in adults is:

To treat ulcerative colitis:

Mild active disease: 2.4 grams (6 tablets of Asacol 400 or 3 tablets of Asacol 800) once daily or in divided doses.

Moderate active disease: 2.4 grams (6 tablets of Asacol 400 or 3 tablets of Asacol 800) up to 4.8 grams (12 tablets of Asacol 400 or 6 tablets of Asacol 800) per day in divided doses.

You may take up to 2.4 grams once a day or in divided doses. If taking more than 2.4 grams a

day, take in divided doses.

To prevent recurrence of ulcerative colitis episodes:

1.2 grams (3 tablets of Asacol 400) up to 2.4 grams (6 tablets of Asacol 400 or 3 tablets of Asacol 800) once daily or in divided doses.

For Crohn's disease:

2.4 grams (6 tablets of Asacol 400 or 3 tablets of Asacol 800) per day in divided doses.

Asacol 400: Do not take more than 12 tablets a day and do not take more than 6 tablets at once.

Asacol 800: Do not take more than 6 tablets a day and do not take more than 3 tablets at once.

Do not exceed the recommended dose.

Take this medicine before meals; swallow it whole, preferably with some liquid. Do not chew, crush or break the tablets before swallowing them. While you are taking this medicine make sure you drink adequate fluids to avoid dehydration, especially after severe or prolonged episodes of vomiting and/or diarrhoea, high fever or heavy sweating. This is to prevent problems with your kidneys.

If you have accidentally taken a higher dose

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

If you forget to take a tablet at the scheduled time, take the dose as soon as you remember, unless it is nearly time to take the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4.Side effects

Like with all medicines, using Asacol may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Organ-specific side effects, affecting the heart, lungs, liver, kidneys, pancreas, skin and subcutaneous tissue have been reported.

Stop taking the medicine immediately and consult your doctor right away:

- if you develop 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
- if you develop unexplained bruising (without injury), bleeding under your skin, purple spots or patches under your skin, anemia (feeling tired, weakness, and looking pale, especially on lips, nails and inside of eyelids), high fever, abdominal pain, headache, sore throat, rash or unusual bleeding (such as nose bleeds).
- lung disease (scarring of lung tissue, allergic reaction) resulting in difficulty in breathing, cough, wheezing and collection of fluids in the lungs, pneumonia
- abnormal liver function tests, hepatitis (inflammation of the liver giving rise to flu-like symptoms and jaundice)
- inflammation of the heart with signs like chest pains or palpitations
- disorder of the immune system (lupus-like syndrome) which can cause inflammation of the heart sac or membranes around the lungs and heart, rash and/or joint pain
- kidney problems (such as inflammation and scarring of the kidneys), kidney failure which may be reversible if treatment is stopped early
- reversible decrease in sperm production

Common side effects (may affect up to 1 in 10 people)

- rash
- indigestion

Uncommon side effects (may affect up to 1 in 100 people)

- fever
- high number of white blood cells called eosinophil granulocytes
- sensation of tingling, pricking and numbness
- hives, itching skin
- chest pain

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

- headache
- dizziness
- diarrhea, stomach pain, flatulence, unpleasant feeling 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 side effects (may affect up to 1 in 10,000 people)

- severe reduction in count of blood cells which can cause weakness, bruising or make infections more likely, low blood cell counts; reduction in blood platelets which increase 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 that cause numbness or tingling
 - inflamed pancreas (associated with pain in the upper abdomen and back and being nauseous)
 - hair loss
 - muscle and joint pain
- Side effects of unknown frequency (frequency cannot be estimated from available data)
- inflammation of the lung membrane (pleurisy)
 - intolerance to mesalazine sometimes with worsening symptoms of the disease
 - weight loss
 - laboratory test results out of normal range

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects, or by using this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

Do not store above 25°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:

- lactose monohydrate
- sodium starch glycolate
- methacrylic acid-methyl methacrylate copolymer (1:2)
- talc micronized

povidone
magnesium stearate
triethyl citrate
ferric oxide red and yellow pigment
macrogol 6000

Each 400 mg tablet contains 76.40 mg lactose monohydrate.

Each 800 mg tablet contains 152.80 mg lactose monohydrate.

What the medicine looks like and contents of the pack

Oblong, reddish-brown tablets. The tablets are available in blister trays of 10 tablets in packs of:

Asacol 400 mg: 100 tablets per pack

Asacol 800 mg: 60 tablets per pack

Registration holder: Tradis Gat Ltd., 32 Shaham St., Petac Tikva.

Manufacturer: Tillotts Pharma, Rheinfelden, Switzerland.

Revised in February 2023 according to MOHs guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Asacol 400 mg: 659925654

Asacol 800 mg: 1333931029