Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Asacol 1600

Modified release tablets

Active ingredient:
Each tablet contains 1600 mg mesalazine

Inactive ingredients and allergens: see 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?

Asacol is indicated:
- For treatment of mild to moderate acute ulcerative colitis.
- For maintenance of disease remission.

Therapeutic group: Anti-inflammatory medicine against bowel inflammation
Asacol is an anti-inflammatory medicine used for the treatment of ulcerative colitis. Ulcerative colitis is a disease in which the wall of the colon or the back passage (rectum) become inflamed (red and swollen). This may lead to frequent and bloody stools, often accompanied by abdominal cramps.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to mesalazine or to any of the other ingredients in this medicine (see section 6).
- You are sensitive (allergic) to salicylates (e.g. acetylsalicylic acid).
- You have severe liver problems.
- You have severe kidney problems.

Special warnings about using this medicine
Before starting treatment with Asacol, tell your doctor if you have any illnesses, particularly if:
- You have any lung problems, e.g. asthma.
- You have impaired function of kidneys, liver or lungs, especially if you are elderly.
- You suffered from allergy to sulphasalazine in the past.

- You had an allergic reaction of the heart, such as inflammation of the heart muscle or heart sac. If you have had previous suspected mesalazine-induced allergic reactions of the heart, then Asacol must not be used. Asacol can be used under supervision if you have had a previous allergic reaction of the heart not caused by mesalazine.
- You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Severe 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 Asacol and seek medical attention immediately if you notice any of the symptoms related to these severe skin reactions described in section 4.

If you have a stomach ulcer, you should use Asacol under supervision.

Kidney stones may develop with use of mesalazine. Symptoms may include pain in the sides of the abdomen and blood in urine. Ensure drinking sufficient amount of liquids during treatment with mesalazine.

Mesalazine may produce red-brown urine discolouration after contact with sodium hypochlorite bleach in the toilet water. This results from a chemical reaction between mesalazine and bleach and is harmless.

Children and adolescents
This medicine is not intended for children or adolescents under 18 years of age. There is no information about the efficacy and safety of the medicine in children and adolescents under 18 years of age.

Tests and follow-up
Before and during intake of Asacol, your doctor may want to check that your liver, kidneys, blood and lungs are working properly.

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- Medicines preventing formation of blood clots (anticoagulants, e.g. warfarin). The effect of these medicines could be increased or decreased, and the effect this may have on you is unclear.
- Medicines affecting the immune system (e.g. azathioprine, 6-mercaptopurine or thioguanine). When used together with Asacol, these medicines may lead to life-threatening infections (see section 4).
- Non-steroidal anti-inflammatory drugs (for example, medicines containing acetylsalicylic acid, ibuprofen or diclofenac)

Using this medicine and food
Asacol can be taken with or without food.

Pregnancy and breastfeeding
There is no sufficient information about use of the medicine during pregnancy. If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, you should consult your doctor or pharmacist before taking this medicine.
Since the medicine is excreted in breast milk in small quantities, due care should be taken if using the medicine while breastfeeding. If the infant develops diarrhoea, breastfeeding should be discontinued.

Driving and using machines
Asacol has a negligible influence on the ability to drive and operate machines. However, if you are affected in any way, you should refrain from driving or operating machines.

Asacol contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say 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 recommended dosage is usually:
Adults
Active phase of disease: When the disease is getting worse, the dosage can be increased up to 4,800 mg (three tablets) daily taken once daily *or* as one tablet 2 to 3 times a day.
Maintenance treatment: dosage of 1600 mg taken daily.
Do not exceed the recommended dose.
The tablets must be swallowed whole, preferably with a glass of water. Do not chew, crush or break the tablets before swallowing. This is important for modified release tablets. If the tablets are not swallowed whole, they may not work as intended.

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 dose at the required time, take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you stop using Asacol
Use Asacol for as long as your doctor prescribed it to you. Talk to your doctor before changing or stopping the treatment.

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

As with any medicine, 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.

Stop using Asacol and seek medical attention immediately if you notice any of the following symptoms:

- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers in the mouth, throat, nose, genitals and eyes, widespread rash, fever and enlarged lymph nodes. These severe skin rash may be preceded by fever and flu-like symptoms.
- Unexplained bruising (without injury), bleeding under the skin, purple spots or purple patches under the skin, anaemia (sensation of tiredness, weakness and pallor, especially in the lips and nails), fever (high temperature), abdominal cramps, acute abdominal pain, sore throat, severe headache or unusual bleeding (e.g. nosebleeds).

Asacol can in very rare cases affect the white blood cells; so, in those cases, the immune system could get worse. If you get an infection with symptoms such as fever with serious worsening of your general condition, or fever with local symptoms of infection such as sore throat/pharynx/mouth or urinary problems, you should immediately see your doctor. Blood tests can then be performed to check for lack of white blood cells (agranulocytosis). It is important that you inform your doctor about all the medications you are taking.

Additional side effects

Common side effects: affect up to 1 in 10 users

- rash
- indigestion

Uncommon side effects: affect up to 1 in 100 users

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

Rare side effects: affect up to 1 in 1,000 users

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

Very rare side effects: affect up to 1 in 10,000 users

- severe reduction in blood cells which can cause weakness, bruising or increase the risk of infections, low blood cell counts; reduction in blood platelets which increases the risk of bleeding
- allergic reactions such as rash
- fever that occurs while taking the medicine and disappears when the medicine is stopped (drug-induced fever)
- immune system disease that can involve organs and joints
- ulcerative colitis involving the entire colon
- abnormal or damaged nerves causing numbness or tingling
- lung disease (scarring of lung tissue, allergic reaction) resulting in difficulty in breathing or wheezing and collection of fluids in the lungs, pneumonia
- pancreas inflammation (associated with pain in the upper abdomen and back and nausea)
- abnormal liver function test results, hepatitis (inflammation of the liver causing flu-like symptoms and jaundice)
- hair loss
- muscle or joint pain
- kidney problems (such as inflammation and scarring of the kidney), kidney failure, which may be reversible if treatment is stopped early
- reversible decrease in sperm production

Side effects of unknown frequency (the frequency of these effects has not been established yet)
- 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
- inflammation of the mucosa surrounding the lungs and the thoracic cavity (pleurisy)
- intolerance to mesalazine and/or exacerbation of disease
- kidney stones and associated kidney pain (see also section 2)
- 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, you should consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use 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 your 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 at a temperature above 30°C.

6. Additional information

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

- microcrystalline cellulose
- methacrylic acid-methyl methacrylate copolymer (1:2)
- sodium starch glycolate (type A)
- hypromellose
- triethyl citrate
- maize starch
- glycerol monostearate (40-55)
- macrogol
- ferric oxide red (E 172)
- polysorbate 80
- colloidal anhydrous silica
- magnesium stearate E 470B
- ferric oxide yellow (E 172)
- potassium dihydrogen phosphate

What the medicine looks like and contents of the pack:
Asacol 1,600 mg modified release tablets are oblong in shape and reddish to brown in colour. The tablets are available in packs containing blisters. The blisters are packed in a carton containing either 30 tablets, 60 tablets or 90 tablets.
Not all pack sizes may be marketed.

Registration holder's name and address:
Tradis Gat Ltd., 32 Shacham St., Petach Tikva 4951727.

Manufacturer's name and address:
Tillotts Pharma GmbH (subsidiary of Tillotts Pharma AG, Switzerland), Warmbacher Strasse 80, 79618 Rheinfelden, Germany.

Revised in January 2024 according to Ministry of Health guidelines.

Registration number of the medicine in the Ministry of Health National Drug Registry:
174-09-36782-99