SCHEDULING STATUS

S3

Asacol 1600, modified-release tablets

Mesalazine

Sugar free

Read all of this leaflet carefully before you start taking Asacol 1600

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- Asacol 1600 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Asacol 1600 is and what it is used for
2. What you need to know before you use Asacol 1600
3. How to use Asacol 1600
4. Possible side effects
5. How to store Asacol 1600
6. Contents of the pack and other information

1. What Asacol 1600 is and what it is used for

Asacol 1600 contains the active substance mesalazine. It is an anti-inflammatory medicine used for the treatment of ulcerative colitis. Ulcerative colitis is a disease in which the lining of the large intestine (colon) or the back passage (rectum) becomes inflamed (red and swollen). This may lead to frequent

and bloody stools, often with abdominal cramps.

Asacol 1600 treats and prevents inflammation throughout the entire colon and rectum (mild to moderate acute ulcerative colitis and for the prevention of relapse).

2. What you need to know before you use Asacol 1600

Do not use Asacol 1600:

- if you are hypersensitive (allergic) to mesalazine or any of the other ingredients of Asacol 1600 (listed in section 6);
- if you are allergic to salicylates (e.g. acetylsalicylic acid);
- if you have severe liver problems;
- if you have severe kidney problems.

Warnings and precautions

Take special care with Asacol 1600:

Talk to your doctor or pharmacist before using Asacol 1600 if you have any medical conditions or illnesses, particularly if you have:

- any lung disease problems, e.g. asthma;
- impaired function of kidneys or lungs, especially if you are elderly;
- suffered an allergy to sulphasalazine in the past;
- had an allergic reaction 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 Asacol 1600 must not be used. Asacol 1600 can be used with care if you have had a previous allergic reaction of the heart not caused by 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.

If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears, contact your doctor immediately.

If you have a stomach ulcer, you should use Asacol 1600 with care.

Kidney stones may develop with use of Asacol 1600. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with Asacol 1600.

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

Before and while you are taking Asacol 1600, your doctor may want to check that your liver, kidneys, blood and lungs are working properly.

Children and adolescents

The use of Asacol 1600 is not recommended in children and adolescents under 18 years, because Asacol 1600 has not been tested in this age group.

Other medicines and Asacol 1600

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- Medicines that prevent the formation of blood clots (anticoagulants, e.g. warfarin). The effect of these medicines could be increased or decreased, the effect this may have on you is unclear.
- Medicines affecting the immune system (e.g. azathioprine, 6-mercaptopurine or thioguanine). Used together with Asacol 1600, 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).

Asacol 1600 with food and drink

Please refer to section 3.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking Asacol 1600.

Since mesalazine is excreted in breastmilk in small quantities, due care should be taken if using Asacol 1600 whilst breastfeeding. If the infant develops diarrhoea, breastfeeding should be discontinued.

Driving and using machines

Asacol 1600 may influence the ability to drive and use machines. If you are affected in any way you should not drive or operate machinery.

3. How to use Asacol 1600

Do not share medicines prescribed for you with any other person.

Always use Asacol 1600 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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 these tablets with modified release, if the tablets are not swallowed whole, they may not work as intended.

Asacol 1600 can be taken with or without food.

Your doctor will decide which dose you should take.

The recommended dose is:

Adults

Active phase of disease

When the disease is getting worse, the dose can be increased up to 4800 mg (three tablets) daily taken once daily or as one tablet 2 to 3 times a day.

Maintenance treatment

1600 mg taken daily.

If you have the impression that the effect of Asacol 1600 is too strong or too weak, talk to your doctor.

If you take more Asacol 1600 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Asacol 1600

If you forget to take a dose at the right time, just take the next dose as normal. Do not take a double dose to make up for forgotten individual doses.

If you stop using Asacol 1600

Use Asacol 1600 for as long as your doctor prescribed it to you. Talk to your doctor before changing or stopping the treatment.

If you have any further questions on the use of Asacol 1600, ask your doctor or pharmacist.

4. Possible side effects

Asacol 1600 can have side effects.

Not all side effects reported for Asacol 1600 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Asacol 1600, please consult your healthcare provider for advice.

If any of the following happens, stop taking Asacol 1600 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.
- 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to Asacol 1600. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- if you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears. These could be symptoms of increased pressure within your skull (idiopathic intracranial hypertension).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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 and nails);
- fever (high temperature);
- acute stomach pain;
- sore throat or unusual bleeding (e.g. nose bleeds).

Asacol 1600 can in very rare cases affect the white blood cells so, in those cases, your 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 taken to check for lack of white blood cells (agranulocytosis). It is important that you inform your doctor about all of your medications.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- rash;
- indigestion.

Less frequent side effects

- high number of white blood cells called eosinophil granulocytes;
- sensation of tingling, pricking and numbness;
- itching skin, hives;
- chest pain;
- headache;
- dizziness;
- inflammation of the heart with signs like chest pain and palpitations;
- diarrhoea, stomach pain, wind (flatulence), feeling if unease and discomfort in the stomach with an urge to vomit and vomiting;
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity);
- 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;
- fever that occurs while taking Asacol 1600 and which disappears when Asacol 1600 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 or tingling;
- lung disease (scarring of lung tissue, allergic reaction) resulting in difficulty in breathing or wheezing and collection of fluid in the lungs, pneumonia;
- 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), kidney failure, which may be reversible if treatment is stopped early;
- reversible decrease in sperm production.

Frequency unknown

- 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 stones and associated kidney pain (see section 2);
- weight loss;
- laboratory results out of normal range.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (sho-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Asacol 1600.

5. How to store Asacol 1600

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

Do not store above 30 °C.

Do not use after the expiry date stated on the blisters.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Asacol 1600 contains

The active substance is mesalazine.

Each modified-release tablet contains 1600 mg mesalazine.

The other ingredients are:

Magnesium stearate E470B

Methacrylic acid methyl methacrylate copolymer (1:2)

Triethylcitrate

Iron oxide yellow (E172)

Iron oxide red (E172)

Macrogol

Microcrystalline cellulose

Glycerol monostearate (40-55)

Hypromellose

Maize starch

Polysorbate 80

Potassium dihydrogen phosphate

Colloidal anhydrous silica

Sodium starch glycolate (type A)

What Asacol 1600 looks like and contents of the pack

Film coated reddish brown oblong tablets with a semi-gloss appearance with dimensions of 23 x 11 x 9 mm.

Holder of Certificate of Registration

Equity Pharmaceuticals (Pty) Ltd

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Route 21 Corporate Park

Nellmapius Drive

Irene

Pretoria

Tel: (012) 345 1747

This leaflet was last revised in

08 September 2025

Registration number

55/11.10/0665

Access to the corresponding translated Patient Information Leaflet:

An electronic copy of the translated Patient Information Leaflet (PIL) is available on the Equity website:

http://www.equitypharmaceuticals.co.za