

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS**

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**ASACOL TABLETS, Mesalazine (5-aminosalicylic acid), 400 mg (tablets)****ASACOL 800, Mesalazine (5-aminosalicylic acid), 800 mg (tablets)****Read all of this leaflet carefully before you start taking ASACOL Tablets**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- ASACOL 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.

1. WHAT ASACOL TABLETS CONTAINS

The active substance is mesalazine (also known as 5-aminosalicylic acid).

ASACOL TABLETS: each tablet contains Mesalazine (5-aminosalicylic acid) 400 mg.

ASACOL 800 Tablets: each tablet contains Mesalazine (5-aminosalicylic acid) 800 mg.

The other ingredients are:

- lactose monohydrate (the 400 mg and 800 mg tablets contain 76,4 mg and 152,8 mg of lactose monohydrate respectively), magnesium stearate (vegetable origin), povidone, sodium starch glycolate (Type A) and talc.
- Film-coating contains:
- Macrogol 6000, methacrylic acid-methylmethacrylatecopolymer, talc, triethyl citrate and iron oxides (yellow pigment and red pigment)

Contains sugar (lactose monohydrate).

2. WHAT ASACOL TABLETS IS USED FOR

ASACOL contains mesalazine. This is an anti-inflammatory medicine used to treat ulcerative colitis.

3. BEFORE YOU TAKE ASACOL TABLETS

Do not take ASACOL tablets:

- If you are allergic (hypersensitive) to mesalazine or any of the other ingredients of ASACOL tablets
- If you are allergic (hypersensitive) to salicylates (e.g. aspirin)
- If you tend to bleed easily or for a longer time than normal
- If you have an ulcer in your stomach or in the first part of the small bowel (duodenum)
- If you have severe kidney problems
- If you have severe liver problems

Take special care with ASACOL tablets:

Please tell your doctor if you have any medical conditions or illnesses, particularly:

- When you start taking ASACOL tablets and during treatment with ASACOL, your doctor may consider regular examinations to check that your blood, liver, kidneys and lungs are normal. It is recommended that you keep all appointments for tests arranged by your doctor. The treatment will be stopped if it affects your liver or kidneys.
- If you have ever had any problems with your kidneys. This is especially important if you are elderly.
- If you have liver problems.
- In elderly patients, ASACOL is only recommended for use if kidney and liver function is normal and caution should generally be exercised.
- If you have any lung problems, e. g. asthma, your doctor may want to check your breathing from time to time.
- Caution is advised in patients with a history of hypersensitivity reactions affecting the heart (myocarditis and pericarditis), irrespective of their cause.
- If you have ever had problems of sensitivity to sulphasalazine, another medicine used to treat ulcerative

colitis and Crohn's ileo-colitis.

- Caution is advised in patients with a history of hypersensitivity reactions and therapy with **ASACOL** should be stopped immediately if symptoms of cramps, abdominal pain, fever, severe headache or rash occur.
- If you keep noticing tablets in your stools, you should consult your doctor.
- Very rarely, serious blood problems have been reported with the use of **ASACOL**. Your doctor may perform regular blood tests when you are taking **ASACOL** tablets to check that your blood counts (the number of cells in the blood) are normal. Further blood tests will be necessary if signs of changes in the blood develop. These signs include:
 - any unexplained bleeding
 - easy bruising and bleeding under your skin
 - a deficiency of red blood cells (anaemia)
 - persistent fever
 - sore throat.

If any of these signs develop, you should stop taking **ASACOL** tablets immediately and tell your doctor.

- If you are a child or younger than 18 years, the safety and effectiveness of **ASACOL** has not been established.
- If you have a stomach or intestinal ulcer, caution should be exercised before starting treatment with **ASACOL** tablets.
- **ASACOL** tablets may interact with other medicines such as warfarin, azathioprine (an immunosuppressant), as well as mercaptopurine and thioguanine (medicines to treat cancer) see "Taking other medicines with **ASACOL**".

Taking ASACOL tablets with food or drink:

You should take the tablets one hour before food intake.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare

professional for advice before taking **ASACOL**.

Safety in pregnancy and breastfeeding has not been established.

Children:

There is only limited documentation for an effect in children (age 6 - 18 years).

Driving and using machinery:

ASACOL tablets may influence your ability to drive and use machines.

Important information about some of the ingredients of ASACOL tablets:

ASACOL tablets contain sugar (lactose). Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **ASACOL**.

Using other medicines with ASACOL tablets:

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

Examples of medicines that may affect, or be affected by, **ASACOL** tablets are:

- Medicines that reduce the activity of the immune system (e. g. azathioprine, 6-mercaptopurine or thioguanine)
- Digoxin (a medicine for the heart)
- Medicines that prevent the formation of blood clots (anticoagulants, e.g., warfarin)
- Medicines that reduce inflammation or pain (known as non-steroidal anti-inflammatory drugs or NSAIDs)
- Sulfinpyrazone (a medicine to treat gout)
- Furosemide, a diuretic (water tablet)
- Lactulose (used for constipation) or similar medicines which change the pH of the stool may prevent release of the active ingredient from **ASACOL** tablets.

4. HOW TO TAKE ASACOL TABLETS

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

Always take **ASACOL** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with **ASACOL** will last. Do not stop treatment early because you think you are cured. If you have the impression that the effect of **ASACOL** is too strong or too weak, talk to your doctor or pharmacist.

ASACOL tablets should be swallowed whole with a glass of water. Do not chew, crush or break the tablets before swallowing them. You may be told to take the tablets at different times, e. g. morning, midday or evening. You can take the tablets one hour before food intake.

Dosage:

ASACOL 400 mg tablets:

To treat ulcerative colitis your daily dose is 6 to 12 tablets once daily or divided in 2 - 3 times daily (as advised by your doctor). 6 tablets may be taken once daily or in divided doses (as advised by your doctor).

Above 6 tablets a day they should be taken in divided doses.

To prevent ulcerative colitis your daily dose is 4 to 6 tablets once daily or in divided doses.

ASACOL 800 mg tablets:

To treat ulcerative colitis your daily dose is 3 to 6 tablets. 3 tablets may be taken once daily or in divided doses (as advised by your doctor). Above 3 tablets a day they should be taken in divided doses.

To prevent ulcerative colitis your daily dose is 2 to 3 tablets once daily or in divided doses.

In the elderly:

The normal dose should be used unless kidney function is impaired.

If you take more ASACOL tablets than you should:

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

You should not take a higher dose than your doctor has prescribed for you. Contact your nearest hospital casualty department or a doctor for advice if you or anyone else has swallowed too many tablets or if you think a child has swallowed any. Take this leaflet, and any tablets that you still have to show the doctor.

Signs and symptoms of overdosage may be:

- sweating
- vomiting
- a loss of water from the body (dehydration) due to the vomiting and sweating
- rapid breathing (hyperventilation)
- fluid on the lungs that can make it difficult to breathe (pulmonary oedema)
- feeling faint or dizzy due to a low concentration of sugar in the blood (hypoglycaemia)

If you forget to take ASACOL tablets:

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.

Effects when treatment with ASACOL is stopped:

Take your tablets for as long as your doctor tells you to. You should talk to your doctor before changing or stopping the treatment otherwise you might risk the benefit of treatment.

5. POSSIBLE SIDE EFFECTS

ASACOL can have side effects. Not all side effects reported for **ASACOL** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **ASACOL**, please consult your doctor, pharmacist or other health care professional for advice.

Stop taking **ASACOL** tablets immediately and tell your doctor if you start to bruise easily, or if you suffer from:

- any unexplained bleeding
- easy bruising and bleeding under your skin (haematomas)

- purple spots or patches under your skin (purpura)
- a deficiency of red blood cells (anaemia)
- persistent fever
- sore throat

Your doctor may need to take a blood test (see “Before you take **ASACOL** tablets”).

Tell your doctor if you notice any of the following:

Frequent side effects

- indigestion
- rash

Less frequent side effects

- a deficiency of red blood cells (anaemia)
- higher than normal level of disease-fighting white blood cells
- a deficiency of granulocytes in the blood, causing increased vulnerability to infection.
- lowered blood cell count
- reduction in number of red and white blood cells as well as platelets (pancytopenia)
- reduction of white blood cells (leucopenia)
- abnormally few neutrophils in the blood (neutropenia)
- deficiency of platelets in the blood (thrombocytopenia)
- ringing sound in ears (tinnitus)
- allergic skin reactions such as a widespread rash
- 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
- paraesthesia (a tingling, prickling or burning sensation of the skin)
- headache

- dizziness
- fever
- flatulence (bloating of the abdomen)
- nausea (feeling sick)
- abdominal pain
- vomiting
- diarrhoea
- joint pain
- hives (urticaria)
- itchy skin (pruritus)
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)
- muscle pain (myalgia) or joint pain
- hair loss (alopecia)
- blood disorders. Symptoms may include weakness, shortness of breath and pale skin, especially the nail beds.
- numbness, tingling, itching and pins and needles feeling in the hand and feet (peripheral neuropathy)
- chest pain, breathlessness, increased heart rate, fever, anxiety
- inflammation of the heart muscle or pericardium (sac surrounding the heart), with symptoms such as chest pain or palpitations.
- kidney disease (e.g. inflammation and scarring of the kidneys), blood in the urine (kidney failure), which may be reversible upon early discontinuation of treatment
- decrease in sperm production (reversible)
- allergic (hypersensitivity) reactions and fibrotic lung reactions. Symptoms may include: difficulty with breathing, cough with phlegm production, coughing of blood, fluid accumulation in the lungs, inflammation of the alveoli, pneumonia
- pain from the upper abdominal to the back (acute pancreatitis)
- increase in liver function tests, dark urine, yellowing of the eyes and skin, abdominal discomfort (hepatitis)

Frequency of side effects unknown

- spinning sensation (vertigo)
- inflammation of the membranes of the pleural cavity surrounding the lungs (pleurisy)
- lung infection, chest pain
- immune system disorders (lupus-like syndrome), which may affect organs (inflammation of both the pericardium and pleura) and joints
- intolerance to mesalazine as contained in **ASACOL** sometimes with worsening symptoms of underlying disease
- loss of appetite, fatigue, bloating and cramping (exacerbation of colitis)
- abnormal liver function tests e.g. increased bilirubin
- severe skin reaction beginning with flu-like symptoms (Stevens-Johnson syndrome)
- skin rash, blistering and redness
- weight loss
- laboratory test results outside the normal range

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. Some side effects may need treatment.

6. STORING AND DISPOSING OF ASACOL TABLETS

- Store at or below 25 °C.
- **KEEP ALL MEDICINES OUT OF REACH OF CHILDREN**
- Do not use the tablets after the expiry date printed on the pack.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF ASACOL TABLETS

ASACOL TABLETS: 90's in clear colourless PVC/aluminium blister packs.

ASACOL 800: 60 or 90 tablets in clear colourless PVC/aluminium blister strip.

Each blister contains 10 **ASACOL** gastro-resistant tablets. The blisters are packed in bundles of 6 or 9 depending on the pack size into cardboard boxes, a package insert is included.

8. IDENTIFICATION OF ASACOL TABLETS

ASACOL TABLETS: An oblong, red-brown enteric-coated tablet.

ASACOL 800: Coated, reddish to brownish oblong tablet with a glossy to matt finish; length 17 mm, width and height 8 mm.

9. REGISTRATION NUMBER

ASACOL TABLETS: S/11.10/171

ASACOL 800: 37/11.10/0629

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Equity Pharmaceuticals (Pty) Ltd.

100 Sovereign Drive

Route 21 Corporate Park

Nellmapius Drive

Irene, Pretoria

Tel nr.: +27 (0) 12 345 1747

11. DATE OF PUBLICATION

Date of Registration:

ASACOL TABLETS: 21 November 1989

ASACOL 800: 01 December 2006

Date of latest revision of text: 18 December 2019

Namibia: NS2 ASACOL 400 mg: 90/11.10/00299 ASACOL 800 mg: 13/11.10/0268

Under licence from Tillotts Pharma AG, Ziefen, Switzerland