

ASACOL®

Mesalazine
400 mg, 800 mg and 1600 mg Enteric Coated Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ASACOL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ASACOL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ASACOL is used for

ASACOL contains the active ingredient mesalazine. This is an anti-inflammatory agent used to treat and prevent further episodes of ulcerative colitis.

Ulcerative colitis is a disease of the large bowel (colon) or back passage (rectum), in which the lining of the bowel becomes inflamed (red and swollen).

ASACOL acts locally at the site of inflammation (colon, rectum and terminal ileum) to reduce this inflammation.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

ASACOL is not addictive.

It is available only with a doctor's prescription.

ASACOL is not expected to affect your ability to drive a car or operate machinery.

Before you take ASACOL

When you must not take it

Do not take ASACOL if you have an allergy to:

- any medicine containing mesalazine
- any of the other ingredients listed at the end of this leaflet
- aspirin or any other salicylates.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take ASACOL if you have:

- severe liver problems
- severe kidney problems.

Do not give this medicine to children and adolescents.

The safety and effectiveness of ASACOL in this age group have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- asthma or lung problems
- liver or kidney problems
- stomach or intestine ulcer
- suffered a reaction after using the similar medicine sulfasalazine
- heart problems such as inflammation of the heart muscle (myocarditis) or sac around heart (pericarditis) after using mesalazine
- severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

ASACOL 400 mg and 800 mg tablets contain a small amount of lactose.

If your doctor has told you that you have intolerance to some sugars, ask your doctor before taking this medicine.

ASACOL may produce red-brown urine discoloration after contact with sodium hypochlorite bleach in the toilet water.

This is caused by a chemical reaction between the active ingredient mesalazine and bleach and is harmless.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking ASACOL.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

ASACOL may interfere with the following types of medicines:

- medicines affecting the immune system or anticancer drugs (e.g. azathioprine or 6-mercaptopurine or thioguanine)
- medicines that prevent the formation of blood clots (anticoagulants e.g. warfarin).
- non-steroidal anti-inflammatory drugs (e.g. medicines containing aspirin, ibuprofen or diclofenac)

How to take ASACOL

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the packaging, ask your doctor or pharmacist for help.

How much to take

The usual dose to treat a current episode of ulcerative colitis is 2.4 g to 4.8 g taken once daily or in divided doses. The dosage may be adjusted by your doctor.

The usual dose to prevent an episode of ulcerative colitis is 1.6 g to 2.4 g taken once daily or in divided doses.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew, crush or break the tablets before swallowing them.

When to take it

The tablets can be taken with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose as normal.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ASACOL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking ASACOL

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ASACOL.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do tests before you start and from time to time while you are taking ASACOL to check that your liver, kidneys, blood and lungs are all right.

Drink plenty of water during treatment.

There have been a few reports of kidney stones. Drinking plenty of water may help to prevent this.

Things you must not do

Do not take ASACOL to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ASACOL.

This medicine helps most people, with ulcerative colitis, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- indigestion
- mild abdominal pain
- diarrhoea
- flatulence
- nausea, vomiting
- mild rash
- increased sensitivity of the skin to sun
- hair loss
- sensation of tingling, pricking and numbness
- headache
- dizziness
- weight loss
- reversible decrease in sperm count in men.

The above list includes less serious side effects of your medicine.

If you notice any of the following, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergic reactions such as rash, itching or hives, shortness of breath, wheezing, coughing, or swelling of limbs, face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing
- 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 which may be accompanied by fever and flu-like symptoms

- severe stomach or abdominal cramps or pain with nausea, vomiting, bloody diarrhoea, fever, severe headache and skin rash
- sudden severe pain in back, side or stomach, pain or burning during urination might be symptoms of kidney stones (see also “Things you must do”)
- liver problems with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine
- muscle aches and pains, joint pain, chest pain (sometimes spreading to the neck and shoulders)
- lung infection with fever, chills, shortness of breath, cough and phlegm.

The above list includes serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects (for example, changes in liver and kidney function or changes in blood test results) can only be found when your doctor does tests from time to time to check your progress.

Tell your doctor if you often observe tablets or tablet shells in your stool while taking ASACOL 400 mg or 800 mg tablets.

There have been a few reports of intact tablets found in the stool in people taking ASACOL 400 mg and 800 mg tablets. What appear to be intact tablets may sometimes be the remains of the tablet coating.

After taking ASACOL

Storage

Keep your tablets in the packaging until it is time to take them.

If you take the tablets out of the packaging, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store ASACOL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can damage some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ASACOL 400 mg, and 800 mg

ASACOL 400 mg and 800 mg tablets are coated, reddish to brownish oblong tablets with a glossy to matt finish.

The dimensions of the 400 mg tablet are: thickness 7 mm, length 15 mm and width: 6 mm.

The dimensions of the 800 mg tablet are: thickness: 8 mm, length: 17 mm and width: 8 mm.

ASACOL 400 mg and 800 mg tablets are supplied in blister packs of 30, 60, 90 or 180 tablets.

ASACOL 1600 mg

ASACOL 1600 mg tablets are coated, dark orange oblong tablets with a glossy to matte finish.

The dimensions of the 1600 mg tablet are: thickness: 9 mm, length: 23 mm and width: 11 mm.

The 1600 mg tablets are supplied in blister packs of 30, 60 or 90 tablets.

Not all pack sizes are marketed.

Ingredients

ASACOL 400 mg, 800 mg and 1600 mg tablets contain mesalazine 400 mg, 800 mg or 1600 mg as the active ingredient.

ASACOL 400 mg, and 800 mg

ASACOL 400 mg and 800 mg tablets also contain the following inactive ingredients:

- sugars as lactose (lactose monohydrate)
- sodium starch glycollate type A
- magnesium stearate
- purified talc
- povidone
- methacrylic acid copolymer
- triethyl citrate
- iron oxide yellow
- iron oxide red
- macrogol 6000.

ASACOL 1600 mg

ASACOL 1600 mg tablets also contain the following inactive ingredients:

- microcrystalline cellulose
- sodium starch glycollate type A
- hypromellose
- colloidal anhydrous silica
- magnesium stearate
- methacrylic acid copolymer
- triethyl citrate
- glycerol monostearate
- maize starch
- polysorbate 80
- macrogol 6000
- iron oxide yellow
- iron oxide red
- monobasic potassium phosphate
- sodium hydroxide.

Supplier

ASACOL is supplied in Australia by:

Chiesi Australia Pty Ltd
Suite 3, 22 Gillman Street
Hawthorn East, VIC 3123

Email:
medicalaffairs.au@chiesi.com
Website: www.chiesi.com.au

Australian registration numbers:

ASACOL 400 mg: AUST R 261419

ASACOL 800 mg: AUST R 261420

ASACOL 1600 mg: AUST R
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