

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I taking ASACOL?

ASACOL contains the active ingredient mesalazine. ASACOL is used to treat and prevent further episodes of ulcerative colitis.

For more information, see Section [1. Why am I using ASACOL?](#) in the full CMI.

### 2. What should I know before I take ASACOL?

Do not take if you have ever had an allergic reaction to mesalazine, aspirin or any other salicylates, or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take ASACOL?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ASACOL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take ASACOL?

- Your doctor will tell you what dose to take each day. Follow the instructions given to you by your doctor or pharmacist.
- Swallow the tablets whole with a glass of water. Do not chew, crush or break the tablets.

More instructions can be found in Section [4. How do I take ASACOL?](#) in the full CMI.

### 5. What should I know while taking ASACOL?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using ASACOL.</li><li>• Keep all of your appointments with your doctor and have all blood tests recommended</li><li>• Drink plenty of water to reduce the chance of getting kidney stones.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• 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.</li><li>• Do not take ASACOL to treat any other complaints unless your doctor tells you to</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• This medicine is not expected to affect your ability to drive a car or operate machinery.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 25°C.</li></ul>

For more information, see Section [5. What should I know while using ASACOL?](#) in the full CMI.

### 6. Are there any side effects?

Less serious common side effects may include: indigestion and mild skin rash.

Serious side effects may include: severe skin rash (blisters, peeling or bruising) with fever or flu-like symptoms; sudden allergic reaction (rash, itching, hives, problems breathing, swollen face, lips, tongue, throat), severe stomach, abdominal, back or chest pain; yellow skin or eyes; pain or burning during urination; strong or recurrent headache, disturbed vision, ringing or buzzing in the ears.

For the full list of side effects and more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ASACOL<sup>®</sup>

Active ingredient: *mesalazine*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ASACOL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ASACOL.**

Where to find information in this leaflet:

- [1. Why am I taking ASACOL?](#)
- [2. What should I know before I take ASACOL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take ASACOL?](#)
- [5. What should I know while taking ASACOL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I taking ASACOL?

ASACOL contains the active ingredient mesalazine.

ASACOL is an anti-inflammatory medicine 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.

### 2. What should I know before I take ASACOL?

#### Warnings

**Do not take ASACOL if:**

- you are allergic to mesalazine, aspirin or any other salicylates, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
- you have severe liver or kidney problems.

**Check with your doctor if:**

- you have any other medical conditions:
  - asthma or lung problems
  - liver or kidney problems
  - stomach or intestine ulcer
- you have suffered any of the following:
  - 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

- a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

### Children and adolescents

Do not give this medicine to children and adolescents below the age of 18 years. The safety and effectiveness of ASACOL in this age group have not been established.

### 3. What if I am taking other medicines?

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

**Some medicines may interfere with ASACOL and affect how it works. These include:**

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

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ASACOL.**

### 4. How do I take ASACOL?

#### 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.
- Swallow the tablets whole with a full glass of water.
- Do not chew, crush or break the tablets before swallowing them.

- Follow the instructions you are given and take ASACOL for as long as your doctor tells you to. 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.

### When to take ASACOL

The tablets can be taken with or without food.

### If you forget to take ASACOL

ASACOL should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

### If you take too much ASACOL

If you think that you have taken too much ASACOL, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while taking ASACOL?

### Things you should do

- 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 to reduce the chance of getting kidney stones. There have been a few reports of kidney stones. Drinking plenty of water may help to prevent this.
- Remind any doctor, dentist or pharmacist you visit that you are using ASACOL.

### Stop taking ASACOL and call your doctor straight away if you:

- develop a skin rash where the skin starts to blister or peel, ulcers in mouth, throat, nose, genitals and eyes
- develop unexplained bruising, bleeding under your skin, purple spots or patches under your skin (see Section [6. Are there any side effects?](#)).

These are serious skin reactions which need urgent medical attention.

### Other things you should know

- 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.
- 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. Tell your doctor if you often observe tablets or tablet shells in your stool.

### Things you should not do

- 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.
- 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.

### Driving or using machines

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

### Looking after your medicine

Store below 25°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### When to discard your medicine

- If your doctor or pharmacist tells you to stop taking this medicine
- If the expiry date printed on the pack has passed
- The packaging is torn or shows signs of tampering.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>Digestive system:</b></p> <ul style="list-style-type: none"> <li>• indigestion</li> <li>• mild abdominal pain</li> <li>• diarrhoea</li> <li>• feeling or being sick (nausea or vomiting)</li> <li>• wind (flatulence)</li> <li>• worsening ulcerative colitis symptoms</li> </ul> <p><b>General body:</b></p> <ul style="list-style-type: none"> <li>• fever</li> <li>• weight loss</li> </ul> <p><b>Lungs:</b></p> <ul style="list-style-type: none"> <li>• lung problems or infection with fever, chills, shortness of breath, cough and phlegm</li> <li>• pain in chest which is worse when breathing in (pleurisy)</li> </ul> <p><b>Muscles and bones:</b></p> <ul style="list-style-type: none"> <li>• muscle aches and pains</li> <li>• joint pain</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>• sensation of tingling, pricking and numbness</li> <li>• headache</li> <li>• dizziness</li> </ul> <p><b>Reproductive system:</b></p> <ul style="list-style-type: none"> <li>• low sperm count in men (reversible)</li> </ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"> <li>• mild skin rash</li> <li>• increased sensitivity of the skin to sun and ultraviolet light (photosensitivity)</li> <li>• hair loss</li> </ul> <p><b>Tests and investigations:</b></p> <ul style="list-style-type: none"> <li>• changes in liver and kidney function</li> <li>• changes in blood test results</li> <li>• increased amylase in the saliva.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Digestive system:</b></p> <ul style="list-style-type: none"> <li>• severe stomach or abdominal cramps or pain with nausea, vomiting, bloody diarrhoea or fever</li> </ul> <p><b>Heart:</b></p> <ul style="list-style-type: none"> <li>• chest pain, sometimes spreading to the neck and shoulders, and sometimes with rash and joint pain</li> </ul> <p><b>Hypersensitivity (allergic) reaction:</b></p> <ul style="list-style-type: none"> <li>• 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</li> </ul> <p><b>Kidney:</b></p> <ul style="list-style-type: none"> <li>• severe pain in back, side or stomach, pain or burning during urination, blood in urine, might be symptoms of kidney stones (see also “Things you should do”)</li> </ul> <p><b>Liver:</b></p> <ul style="list-style-type: none"> <li>• liver problems with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>• strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears which might be symptoms of increased pressure within your skull (idiopathic intracranial hypertension)</li> </ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• 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</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What ASACOL contains

<b>Active ingredient (main ingredient)</b>	mesalazine
<b>Other ingredients (inactive ingredients)</b>	<b>400 mg and 800 mg tablets</b> <ul style="list-style-type: none"><li>• lactose monohydrate</li><li>• magnesium stearate</li><li>• povidone</li><li>• purified talc</li><li>• sodium starch glycollate Type A</li><li>• film coating contains: iron oxide red, iron oxide yellow, macrogol 6000, methacrylic acid copolymer and triethyl citrate.</li></ul> <b>1600 mg tablets</b> <ul style="list-style-type: none"><li>• colloidal anhydrous silica</li><li>• hypromellose</li><li>• magnesium stearate</li><li>• microcrystalline cellulose</li><li>• sodium starch glycollate Type A</li><li>• film coating contains: glyceryl monostearate, iron oxide red, iron oxide yellow, macrogol 6000, maize starch, methacrylic acid copolymer, monobasic potassium phosphate, polysorbate 80, sodium hydroxide and triethyl citrate.</li></ul>
<b>Potential allergens</b>	ASACOL 400 mg and 800 mg tablets contain a small amount of lactose.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What ASACOL looks like

#### ASACOL 400 mg and 800 mg tablets

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 tablets are not currently available.

ASACOL 800 mg tablets are supplied in blister packs of 90 tablets\*.

ASACOL 400 mg: AUST R 261419

ASACOL 800 mg: AUST R 261420

#### ASACOL 1600 mg tablets

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 60 tablets\*.

ASACOL 1600 mg: AUST R 322671

\*Other pack sizes are not currently available.

### Who supplies ASACOL

Chiesi Australia Pty Ltd  
Level 7, Suite 1, 500 Bourke Street,  
Melbourne, VIC 3000.

Email: [medinfo.au@chiesi.com](mailto:medinfo.au@chiesi.com)

Website: [www.chiesi.com.au](http://www.chiesi.com.au)

This leaflet was prepared in May 2025.

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