

ASACOL

**Mesalazine 400mg
enteric coated
tablets**

**Mesalazine 800mg
enteric coated
tablets**

**Mesalazine
16.67%w/w (500mg)
suppositories**

What is in this leaflet

Please read this leaflet carefully before you start using ASACOL.

Keep this leaflet. You may need to read it again.

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. If you have any further questions, ask your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your using

ASACOL against the benefits expected for you. If you have any concerns about being given this medicine, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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.

What ASACOL is used for

ASACOL enteric coated tablets contain 400mg mesalazine or 800mg mesalazine, which is a gastrointestinal anti-inflammatory drug. The tablets are enteric coated and gastro-resistant, i.e., they pass through the stomach undissolved to deliver their content to the large bowel and rectum. These are the anatomical regions where inflammatory bowel disease such as ulcerative colitis is localised.

ASACOL enteric coated tablets are used for the treatment and prevention of relapse of inflammatory intestinal diseases, such as ulcerative or idiopathic colitis and Crohn's disease.

ASACOL suppositories contain 500mg (16.67% w/w) of the gastrointestinal anti-inflammatory drug mesalazine finely dispersed in hard fat.

ASACOL suppositories are used for the treatment and prevention of relapse of mild to moderate ulcerative colitis in the rectum.

Ulcerative colitis and Crohn's disease are diseases 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 and rectum) to reduce this inflammation.

The tablets can also be used to prevent further episodes of ulcerative colitis and Crohn's disease.

The suppositories can also be used to prevent

further episodes of mild to moderate ulcerative colitis in the rectum.

Your doctor may have prescribed ASACOL for another reason.

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

ASACOL is available only with a doctor's prescription.

Before you use ASACOL

What points should be considered?

No dose recommendations for children and adolescents are available.

When you must not take ASACOL enteric coated tablets or ASACOL suppositories:

- 1. If you are hypersensitive (allergic) to salicylates.**
- 2. If you are hypersensitive (allergic) to mesalazine or any of the other ingredient.**

3. If you have severe kidney problems.

4. If you have severe liver problems.

5. This medicine should not be taken by children under 2 years of age.

If you are not sure whether you should start using ASACOL, talk to your doctor.

Before you start to take ASACOL enteric coated tablets or ASACOL suppositories:

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

1. If you have ever had any problems with your kidneys.

This is especially important if you are elderly. When you start taking ASACOL, your doctor may test your blood before starting Asacol and regularly during treatment to check that your kidneys work properly.

2. If you have an ulcer in your stomach or in the first part of the small bowel

(duodenum), tell your doctor.

3. If you ever have had allergic reactions affecting your heart (myocarditis and pericarditis).

4. If you have been informed about increased liver enzyme levels.

5. If you have any lung problems, e.g. asthma, your doctor may want to check your breathing from time to time.

6. If you have a history of adverse reactions to sulphasalazine (another drug to treat ulcerative colitis). ASACOL therapy should be initiated only under close medical supervision. Treatment must be stopped immediately if acute symptoms of intolerance occur such as abdominal (stomach) cramps, severe abdominal pain, fever, severe headache and rash.

7. If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis 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.

8. Very rarely, serious blood problems have been reported with the use of this medicine.

Your doctor may perform regular blood tests when you are taking ASACOL 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 (e.g. nosebleeds)
- easy bruising
- purple spots or patches
- persistent fever
- sore throat

- a deficiency of red blood cells (anaemia)

9. Asacol contains milk sugar (lactose)

Patients who are intolerant to lactose should note that ASACOL contains a small amount of lactose. If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking this medicine.

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

If you are not sure whether you should be taking ASACOL, talk to your doctor.

There are a limited number of reports of intact tablets appearing in the stool. These seemingly intact tablets may, in some cases, represent largely empty shells from the coated tablets. If you keep noticing tablets in your stools, you should consult your doctor.

There have been a few reports of kidney stones.

Drink plenty of water during treatment.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription from a pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking ASACOL.

Tell your doctor about all the illnesses you have as well as any medicines used for their treatment, because they may interfere with the effects of ASACOL or necessitate a different dosage requirement.

Examples of drugs that may affect, or be affected by, ASACOL are:

- drugs that reduce the activity of the immune system (e.g. azathioprine, 6-mercaptopurine or thioguanine)
- drugs that prevent the formation of blood clots (anticoagulants, e.g. warfarin).

These medicines may be affected by ASACOL, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ASACOL.

Using ASACOL with food and drink

ASACOL Enteric coated tablets

Swallow the tablets whole and drink a glass of water. Take the tablets before food intake.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

ASACOL has no relevant effects on the ability to drive or use machines.

How to use ASACOL

How much to take: ASACOL enteric coated tablets

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

To treat ulcerative colitis:

2400mg to 4800mg mesalazine) per day in individual doses.

To prevent an episode of ulcerative colitis:

1200mg to 2400mg mesalazine per day, once daily or in divided doses.

To prevent an episode of Chron`s ileo-colitis:

2400mg per day in divided doses.

Your doctor will determine the dosage that is most suitable for you. Do not change the prescribed dose by yourself.

The tablets must be taken whole preferably with a glass of water. The tablets must not be

chewed, crushed or broken under any circumstances. If possible, they should be taken before a meal with a glass of liquid. You should have regular meals during treatment to ensure the passing of the medicine to the target area in the intestine.

Elderly people:

No dose adjustment is required unless your liver or kidney function is impaired.

Children and adolescents:

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

ASACOL is only recommended for use in children 6 years and older. The actual dose will vary as it is determined individually based on the disease phase and the child`s weight in kilograms. For further information please talk to your doctor.

How much to take: ASACOL suppositories

The usual dose for adults is 1 to 2 suppositories inserted up to three times daily

i.e.: up to 6 suppositories per day into the rectum (after a bowel movement). For children according to the doctor's discretion. Your doctor will determine the dosage that is most suitable for you. Do not change the prescribed dose by yourself.

Always use ASACOL exactly as your doctor has told you. ASACOL suppositories must not be swallowed. They should be inserted deep into the back passage after a bowel movement. You should check with your doctor or pharmacist if you are not sure.

Elderly people:

No dose adjustment is required unless your liver or kidney function is impaired.

Children:

There is little experience and only limited documentation for an effect in children.

Instructions for use

1. Wash your hands.
2. Remove the plastic wrapper round the suppository.
3. Lie on your side and draw your knees up. Insert the suppository

- as far as possible into the rectum with the pointed end first. The round end then fits closely to the anus and avoids unnecessary irritation.
4. Stretch your legs out and stay lying down for a few minutes.

For the medicine to work in the best possible way, you should avoid evacuating your bowel for as long as possible after inserting the medicine, preferably for eight hours after administration.

If you take more ASACOL than you should

You should not take a higher dose than your doctor has prescribed for you. Contact your doctor, pharmacist, hospital or Poisons Information Centre (telephone 0800 POISON or 0800 764 766) if you have taken more ASACOL than prescribed in this information or by your doctor.

Common symptoms of overdose are:

- excessive sweating
- vomiting
- rapid breathing
- feeling faint or dizzy.

If you forget to take ASACOL

If you forget to take your ASACOL dose at the right time, just take the next dose as normal.

Do not take a double dose to make up for a forgotten dose.

If you stop taking ASACOL

Take your ASACOL for as long as your doctor tells you to. You should talk to your doctor before changing or stopping the treatment.

If you think that the effect of ASACOL is too strong or too weak, you should consult your doctor or pharmacist about this.

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

While you are using ASACOL

Things you must do

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

Things you must not do

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your 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.

Side effects

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

In addition to the beneficial effects of ASACOL, like all medicines, ASACOL

enteric coated tablets and ASACOL suppositories can cause side-effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have. Stop taking ASACOL enteric coated tablets or suppositories immediately and tell your doctor if you bruise easily, or if you suffer from:

- **any unexplained bleeding** (e.g. nosebleeds)
- purple spots or patches
- persistent fever
- a deficiency of red blood cells (anaemia), you feel tired, weak and turn pale, especially at the lips, nails and inside the eyelids
- sore throat.
- 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. These serious skin rashes can be preceded by

fever and flu-like symptoms.

Your doctor may need to take a blood test (see section "Precautions").

The following frequencies are used for evaluating side effects:

Very common: In more than 1 in 10 patients treated

Common: In less than 1 in 10, but more than 1 in 100 patients treated

Uncommon: In less than 1 in 100, but more than 1 in 1,000 patients treated

Rare: In less than 1 in 1,000, but more than 1 in 10,000 patients treated

Very rare: In less than 1 in 10,000 patients treated, including isolated cases

Not known: Cannot be estimated from the available data.

The following side effects were reported during clinical studies with ASACOL tablets:

Common

Rash, indigestion

Uncommon

Fever, high number of white blood cells called eosinophil granulocytes, sensation of tingling, pricking and numbness,

hives, itching skin, chest pain.

Rare

Headache, dizziness, inflammation of the heart with signs like chest pains or palpitations, diarrhoea, stomach pain, wind (flatulence), feeling of unease, increased sensitivity of the skin to sun and discomfort in the stomach with an urge to vomit and vomiting

Very rare

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 or skin eruption, 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, 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 and 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

Not known

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 membranes of the pleural cavity surrounding the lungs (pleurisy), kidney stones, intolerance to mesalazine sometimes with worsening symptoms of underlying disease, weight loss, laboratory test results out of normal range.

An unknown number of the above side effects

are probably due more to the underlying, chronic inflammatory bowel disease rather than to treatment with ASACOL. This is especially true for side effects of the gastrointestinal tract.

The following side effects were reported during clinical studies with ASACOL suppositories

Rare

Headache, dizziness, inflammation of the heart with signs like chest pains or palpitations, diarrhoea, stomach pain, wind (flatulence), feeling of unease, increased sensitivity of the skin to sun and discomfort in the stomach with an urge to vomit and vomiting

Very rare

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 or skin eruption, 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, abnormal or damaged nerves giving a sensation of numbness and tingling, lung disease (scarring of lung tissue, allergic reaction) resulting in difficulty in breathing or wheezing and collection of fluid in the lungs, 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 and joint pain, kidney problems (such as inflammation and scarring of the kidney), reduced kidney function, reversible decrease in sperm production

Not known

inflammation of the membranes of the pleural cavity surrounding the lungs (pleurisy), intolerance to mesalazine sometimes with worsening symptoms of underlying disease, local reaction.

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.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Ask your doctor or pharmacist if you do not understand anything in this list.

Further information can be obtained from your doctor or pharmacist, who have access to the detailed prescribing information.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking ASACOL

Storage

Do not store above 25°C.

Store in the original package in order to protect from moisture.

ASACOL suppositories should also be stored away from direct sunlight.

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What ASACOL enteric coated tablets contain

One ASACOL 400mg tablet contains 400mg mesalazine.

One ASACOL 800mg tablet contains 800mg mesalazine.

The other ingredients are: lactose, colouring E172 (iron oxide) and other ingredients.

**What ASACOL
suppositories
contain**

One ASACOL
suppository contains
500mg mesalazine.

The other ingredient is:
hard fat.

**Where can you get
ASACOL?**

At pharmacies on
medical prescription only.

**What ASACOL
looks like and
contents of the pack**

ASACOL 400mg enteric
coated tablets: reddish-
brown coated tablets,
100 tablets.

ASACOL 800mg enteric
coated tablets: reddish-
brown coated tablets, 90
or 180 tablets.

ASACOL 16.67% w/w
(500mg) suppositories:
light grey brown
torpedo-shaped
suppository, 20
suppositories in each
carton.

Distributor

ASACOL is distributed in
New Zealand by:

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