

Consumer Medicine Information

ASACOL

Mesalazine

400 mg gastro-resistant tablets

500 mg suppositories

Read all of this leaflet carefully before you start using ASACOL

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

If you have any further questions, 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.

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What ASACOL is and what it is used for

ASACOL tablets contain 400 mg mesalazine, which is a gastrointestinal anti-inflammatory drug. The tablets are 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 gastro-resistant 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 500 mg 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.

Before you take ASACOL

Do not take ASACOL gastro-resistant tablets or 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.**

Take special care with ASACOL gastro-resistant tablets and suppositories:

Please tell your doctor 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 regularly 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 of your heart.**
4. **If you have been informed about increased liver enzyme levels.**
5. **If you are allergic 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 cramps, abdominal pain, fever, severe headache or rash.
6. **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:

- **unexplained bleeding** (*e.g. nosebleeds*)
- easy bruising
- purple spots or patches
- persistent fever
- sore throat.

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

A limited number of reports of intact tablets in stool have been received. If you observe tablets in your stool repeatedly, you should consult your doctor.

Using 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. 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 inflammation or pain [non-steroidal anti-inflammatory drugs (NSAID)]

- Drugs that reduce the activity of the immune system (e.g. azathioprine or 6-mercaptopurine)
- The anti-cancer drug methotrexate
- Drugs that prevent the formation of blood clots (anticoagulants, e.g. warfarin).

Using ASACOL with food and drink

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

Pregnancy and breast-feeding

To date, there is limited experience of the use of mesalazine products during pregnancy and breast-feeding. Small amounts of mesalazine are passed via the placenta into the foetal circulation. Low concentrations of mesalazine and its N-acetyl metabolite have been detected in breast milk during oral treatment. The clinical significance of this has not been determined. Caution should be exercised when mesalazine is administered to nursing mothers. If you are pregnant or breast-feeding or if you are planning to become pregnant during the treatment, consult your doctor about the use of ASACOL gastro-resistant tablets or ASACOL suppositories.

Driving and using machines

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

Important information about some of the ingredients in ASACOL gastro-resistant tablets

ASACOL gastro-resistant tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, for example lactose, contact your doctor before taking this medicinal product.

How to use ASACOL

ASACOL gastro-resistant tablets

Always use ASACOL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose for adults is 400-800 mg 2 to 4 times a day. Your doctor will determine the dosage that is most suitable for you.

The tablets should be swallowed whole with a glass of water. 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 kidney function is impaired.

Children:

There is no dose recommendation for children.

ASACOL suppositories

The usual dose for adults is 1 to 2 suppositories inserted up to three times daily ie: up to 6 suppositories per day into the rectum. For children according to the doctor's discretion. Your doctor will determine the dosage that is most suitable for you. Always use ASACOL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Elderly people:

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

Children:

There is no dose recommendation for 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 if you have taken more ASACOL than prescribed in this information or by your doctor (and you do not feel well).

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 a 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.

Possible Side Effects

Like all medicines, ASACOL gastro-resistant tablets and ASACOL suppositories can cause side-effects, although not everybody gets them. Evaluation of the side effects is based on the following frequencies:

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

Stop taking ASACOL gastro-resistant 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
- sore throat.

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

The following side effects were reported during clinical studies with Asacol tablets and Asacol suppositories.

Serious side effects

Uncommon:

- low number of red blood cells (anaemia)

Non-serious side effects

Very common:

- headache

Common:

- skin rash
- feeling dizzy (dizziness)
- feeling sick (nausea)
- indigestion (dyspepsia)
- abdominal pain
- vomiting
- diarrhoea
- joint pain (arthralgia)
- drug fever (fever that occurs while taking the medicine and which disappears when the medicine is stopped)

Uncommon:

- feeling of pins and needles (paresthesia)
- buzzing, ringing or whistling in the ears (tinnitus)
- flatulence
- itching skin (pruritus)
- hives (urticaria)
- muscle pain (myalgia)
- no drug effect

The following undesirable effects were noticed from spontaneous reporting or the literature. The frequency is therefore not known.

Serious side effects

- difficulty breathing (dyspnoea)
- chest pain
- lung disorders such as inflammation of the lungs (pneumonia)
- inflammation of the heart muscle (myocarditis) or heart sac (pericarditis)
- blood disorders, including:
 - low number of white blood cells (leucopenia, neutropenia), which sometimes can be severe (agranulocytosis)
 - low numbers of all blood cells (pancytopenia)
 - low number of platelets (thrombocytopenia)
 - elevated number of eosinophil granulocytes in the blood (eosinophilia)
 - bone marrow depression (aplastic anaemia)
- worsening of the symptoms of colitis
- inflammation of the pancreas (pancreatitis)
- liver problems, such as
 - abnormal liver function tests (blood tests to investigate how well the liver is working)
 - inflammation of the liver (hepatitis)

- lupus-like syndrome. This is a disorder of the immune system which can cause:
 - pericarditis (an inflammation of the membrane around the heart)
 - pleuropericarditis (an inflammation of the membranes around the lungs and heart)
 - rash
 - joint pain (arthralgia)
- inflammation of the kidneys (interstitial nephritis)
- nephrotic syndrome
- renal failure, which may be reversible on stopping the medicine

Non-serious side effects

- cough
- hair loss (alopecia)

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.

After taking ASACOL

Do not store above 25°C.

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

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.

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.

Further Information

What ASACOL gastro-resistant tablets contain

The active substance is mesalazine. One tablet contains 400 mg mesalazine.

The other ingredients are lactose monohydrate, sodium starch glycolate (type A), magnesium stearate, talc, povidone, metacrylic acid-methyl metacrylate copolymer, triethyl citrate, iron oxide yellow (E 172), iron oxide red (E 172), macrogol

What ASACOL suppositories contain

The active substance is mesalazine. One suppository contains 500 mg mesalazine.

The other ingredient is hard fat.

What ASACOL looks like and contents of the pack

ASACOL 400 mg gastro-resistant tablets: reddish- brown coated tablets, 100 tablets.
ASACOL 500 mg suppositories: light grey brown torpedo-shaped suppository, 20 suppositories in each carton.

Distributor

ASACOL is distributed by:

Baxter Healthcare Limited
P O Box 14-062
Panmure
Auckland 1741
NEW ZEALAND

Customer enquiries phone: (09) 574 2400

Manufacturer

Haupt Pharma Wülfing GmbH
Bethelner Landstrasse 18
D-31028 Gronau
GERMANY.

This leaflet was prepared 24 November 2009.

ASACOL is a trade name of Tillotts Pharma AG, Switzerland.

Reference: New Zealand datasheet dated 22 October 2009.