Consumer Medicine Information

ASACOL

Mesalazine 400mg enteric coated tablets
Mesalazine 800mg enteric coated tablets
Mesalazine 500mg (16.67%w/w) suppositories

Read all of 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 is in this leaflet

What ASACOL is and what ASACOL is used for.

Before you use ASACOL.

How to use ASACOL.

Possible side effects.

How to store ASACOL.

Further information.
What ASACOL is and 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 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 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 use ASACOL

Do 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.
Take special care with ASACOL enteric coated tablets and ASACOL 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 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. 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)

8. 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.

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 from a pharmacy, supermarket or health food shop.

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).

**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 or negligible influence on the ability to drive or use machines.

**Important information about some of the ingredients in ASACOL enteric coated tablets**

ASACOL enteric coated 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 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.

The tablets must be swallowed whole preferably 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 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.

**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. 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. ASACOL suppositories must not be swallowed. They should be inserted into the back passage. 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 overdosage 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.
Possible Side Effects

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.

Evaluation of the side effects is based on the following frequencies:

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Very common:</td>
<td>In more than 1 in 10 patients treated</td>
</tr>
<tr>
<td>Common:</td>
<td>In less than 1 in 10, but more than 1 in 100 patients treated</td>
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<tr>
<td>Uncommon:</td>
<td>In less than 1 in 100, but more than 1 in 1,000 patients treated</td>
</tr>
<tr>
<td>Rare:</td>
<td>In less than 1 in 1,000, but more than 1 in 10,000 patients treated</td>
</tr>
<tr>
<td>Very rare:</td>
<td>In less than 1 in 10,000 patients treated, including isolated cases</td>
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</tbody>
</table>

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)
- 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.

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 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
- weight loss
- laboratory test results out of normal range
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 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

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.

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

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

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**After taking ASACOL**

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.

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.

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**Further Information**

**What ASACOL enteric coated tablets contain**

The active substance is mesalazine. One tablet contains 400mg mesalazine or 800mg mesalazine.

The other ingredients are lactose monohydrate, sodium starch glycolate (type A), magnesium stearate, talc, povidone, methacrylic acid-methyl metacrylate copolymer (eudragit S), triethyl citrate, iron oxide yellow (E 172), iron oxide red (E 172), macrogol 6000.

**What ASACOL suppositories contain**

The active substance is mesalazine. One suppository contains 500mg (16.67%w/w) mesalazine.

The other ingredient is hard fat.

**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, 60, 90 or 180 tablets.
ASACOL 500mg suppositories: light grey brown torpedo-shaped suppository, 20 suppositories in each carton.

**Distributor**

ASACOL is distributed by:

Baxter Healthcare Limited
PO Box 14062
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 22 May 2014.

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

Reference: New Zealand ASACOL datasheet dated 22 May 2014.