

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Asacol® 400mg MR tablets
(mesalazine)

Read all of this leaflet carefully before you start taking this medicine

- 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.

In this leaflet:

1. What Asacol 400mg MR tablets are and what they are used for
2. Before you take Asacol 400mg MR tablets
3. How to take Asacol 400mg MR tablets
4. Possible side effects
5. How to store Asacol 400mg MR tablets
6. Further information

1. WHAT ASACOL 400MG MR TABLETS ARE AND WHAT THEY ARE USED FOR

Asacol 400mg MR tablets contain the active substance mesalazine (also known as 5-aminosalicylic acid) which is an anti-inflammatory drug used in the treatment of:

- **Ulcerative colitis** - a disease of the large bowel (colon) and back passage (rectum) in which the lining of the bowel becomes inflamed (red and swollen). Symptoms can include rectal bleeding, frequent diarrhoea and abdominal pain. Asacol 400mg MR tablets act locally in the colon to reduce inflammation and can also prevent further episodes (flares) of ulcerative colitis.
- **Crohn's ileo-colitis** – a disease affecting the small bowel (terminal ileum) and colon in which the lining of the bowel becomes swollen and sore. This may lead to the development of ulcers, abscesses and narrowing (strictures) in the bowel. Asacol 400mg MR tablets act locally in the terminal ileum and colon to control the disease and prevent further flares of Crohn's ileocolitis.

2. BEFORE YOU TAKE ASACOL 400MG MR TABLETS

Do not take Asacol 400mg MR tablets if you:

- are allergic (hypersensitive) to any of the ingredients in the product (*see Section 6 on 'What Asacol 400mg MR tablets contain'*)
- are allergic to aspirin or any other salicylate
- have had kidney problems or blood abnormalities while taking other medicines such as sulphasalazine
- have severe kidney impairment.

DO NOT give the tablets to children under 2 years of age.

TELL YOUR DOCTOR BEFORE USING mesalazine:

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

Asacol may produce red-brown urine discoloration after contact with sodium hypochlorite bleach in the toilet water. It concerns a chemical reaction between mesalazine and bleach and is harmless.

Take special care with Asacol 400mg MR tablets

- Asacol should be used with extreme caution in patients with confirmed mild to moderate kidney impairment.
- Asacol should be used with caution in the elderly.

Serious skin reactions including Drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) 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 described in section 4.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription. Asacol 400mg MR tablets should NOT be taken with **Lactulose** (a medicine for constipation).

Use of **non-steroidal anti-inflammatory drugs** (NSAIDs such as ibuprofen, aspirin, Cox-II inhibitors) and **azathioprine** in particular may increase the risk of kidney reactions.

Pregnancy and breast-feeding

Women who are pregnant or breast-feeding should not take Asacol 400mg MR tablets unless advised otherwise by their doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Tests on your liver, kidney and blood

Before you start treatment with Asacol 400mg tablets you will have a blood and urine test to check how well your kidneys are working and what your blood is doing. During treatment your doctor will check how well your liver, kidney and blood is working by taking blood and urine sample periodically during your treatment.

Kidney stones may develop with use of mesalazine. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with mesalazine.

Driving and using machines

Asacol 400mg MR tablets are not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Asacol 400mg MR tablets

Patients who are intolerant to **lactose** should note that Asacol 400mg tablets contain 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.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, i.e. is essentially “sodium-free”.

3. HOW TO TAKE ASACOL 400MG MR TABLETS

Always take Asacol 400mg MR tablets exactly as your doctor has told you. You should check with your doctor if you are not sure.

The tablets should be swallowed whole with water; do not break, crush or chew them.

Whilst taking this medicine ensure you drink adequate fluids to remain well hydrated, especially after severe or prolonged episodes of vomiting and /or diarrhoea, high fever or heavy sweating. This is to avoid problems with your kidneys.

The usual dose is:

- **Treating ulcerative colitis** - 6 tablets each day divided throughout the day. For example:
 - 2 tablets 3 times a day OR
 - 3 tablets twice a day.

- **Preventing further episodes of ulcerative colitis**
 - between 3 and 6 tablets once daily or divided throughout the day. For example:
 - a daily dosage of 3 tablets may be taken as 3 tablets once a day or 1 tablet 3 times a day
 - a daily dosage of 6 tablets may be taken as 6 tablets once a day or 3 tablets twice a day.

- **Preventing further episodes of Crohn's ileo-colitis** – between 3 and 6 tablets divided throughout the day. For example:
 - a daily dosage of 3 tablets may be taken as 1 tablet 3 times a day
 - a daily dosage of 6 tablets may be taken as 3 tablets twice a day.

DO NOT take more than 6 tablets a day.

Asacol 400mg MR tablets are not recommended for use in children.

If you stop taking Asacol 400mg MR tablets

Keep taking the tablets for as long as your doctor tells you. Your symptoms may come back if you stop treatment too early. Remember to get a repeat prescription at the right time so that you do not miss a day of treatment.

If you take more Asacol 400mg MR tablets than you should

Do not exceed the recommended dose. You should only take as many tablets as your doctor has instructed on the pharmacist's label. If you take too much medicine, tell your doctor immediately or go to your nearest Accident & Emergency Department. Take the tablet pack with you if possible.

If you forget to take Asacol 400mg MR tablets

If you forget to take a dose at the required time, take it as soon as you remember and continue taking your tablets as before. DO NOT take more than two doses in one hour. If it is almost time for your next dose, wait until then and carry on as before.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Asacol 400mg MR tablets can cause side effects, although not everybody gets them.

Allergic reactions can occur. **Tell your doctor** if you get:

- a rash with or without itching, any shortness of breath, palpitations (rapid heart beat) or chest pain. These effects will usually disappear when you stop taking the medicine. Stop using mesalazine and seek medical attention immediately if you notice any of the following symptoms:

- 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. These serious skin rashes can be preceded by fever and flu-like symptoms.

Tell your doctor immediately

if you experience any of the following symptoms:

- fever, sore throat, mouth or lip ulcers, spots underneath your skin anywhere on your body, including the genital and anal regions, become very pale, swollen ankles or have unusual bleeding (e.g. unexpected nosebleeds or bleeding gums)
- skin rash with flaking, boils or sore lips or mouth
- bruising more easily or suspect blood abnormalities
- problems with kidney function

Common side effects (*in more than 1 in 100 people but less than 1 in 10 people*):

- diarrhoea
- abdominal pain
- nausea (feeling sick)
- headache.

Rare side effects (*in less than 1 in 1000 people*):

- problems with heart, lung, liver or kidney function
- inflammation of the pancreas
- blood abnormalities
- numbness and tingling of the fingers and toes due to damaged nerves
- hair loss
- fever
- skin rash.

Very rare side effects (*in less than 1 in 10,000 people*):

- worsening of symptoms of colitis
- Erythema multiforme and Stevens-Johnson syndrome (skin and mucous membrane

disease).

Not known (*frequency cannot be estimated from available data*)

- Inflamed lining of the lung, causing sharp chest pain that feels worse with breathing, dry cough, shortness of breath (pleurisy)
- Kidney stones and associated kidney pain (see also section 2)
- Increased pressure in brain: headache which may originate behind your eyes and worsen with eye movements, with blurred or dimmed vision, double vision, seeing light flashes, difficulty seeing to the side, and brief or permanent vision loss. These may be associated with dizziness, nausea, vomiting, ringing in ears.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom (Northern Ireland)

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ASACOL 400MG MR TABLETS

Keep out of the sight and reach of children.

Store Asacol 400mg MR tablets in their original pack below 25°C (77°F) in a dry place, protected from direct sunlight.

Do not remove the moisture absorbing pouch from the bottle. The pouch is not part of your medicine and is marked DO NOT EAT. Keep the bottle tightly closed.

Do not use Asacol 400mg MR tablets after the expiry date which is stated on the pack after 'Exp'. 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.

6. FURTHER INFORMATION

What Asacol 400mg MR tablets contain

The **active** substance is mesalazine (also known as 5-aminosalicylic acid). Each tablet contains 400mg mesalazine.

The **other** ingredients are

Core: lactose monohydrate, sodium starch glycollate, magnesium stearate, talc, povidone.

Coating: methacrylic acid-methyl methacrylate copolymer (1:2), dibutyl sebacate, ferric oxide yellow (E172), ferric oxide red (E172) and macrogol 6000.

See also Section 2 on 'Important information about some of the ingredients of Asacol 400mg MR tablets'.

What Asacol 400mg MR tablets look like and contents of the pack

Asacol 400mg MR tablets are red-brown, coated and oblong shaped. They are packed in a plastic bottle with a child-resistant closure that contains a cotton/silica gel moisture absorbing pouch. Asacol 400mg MR tablets are available in packs of 84, 90, 120 or 168 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder

AbbVie Ltd.
Maidenhead
SL6 4UB
UK

Manufacturer

Warner Chilcott
Deutschland GmbH
Dr.-Otto-Röhm-Straße 2-4
64331 Weiterstadt, Germany.

or

Allergan Pharmaceuticals
International Limited
Clonsaugh Business &
Technology Park,
Dublin 17, D17 E400, Ireland

Getting more advice about ulcerative colitis or Crohn's ileo-colitis

In addition to advice and information available from your doctor and pharmacist, you may wish to contact Crohn's and Colitis UK for Colitis and Crohn's Disease which offers information, advice and local support groups.

Crohn's and Colitis UK, 4 Beaumont House, Sutton Road, St Albans, Herts., AL1 5HH

Telephone Information Line:

0845 130 2233 (Monday to Friday 10am - 1pm)

Crohn's and Colitis Support Line:

0845 130 3344 (Monday to Friday 1.00pm- 3.30pm / 6.30pm - 9pm)

Large print, braille, audio format leaflet

To obtain this leaflet in large print, braille or audio format, please call the following freephone number: 0800 198 5000.

Asacol® is a Trademark

Marketing Authorisation Number:

PL 41042/0053

This leaflet was last revised in

May 2023