

**PACKAGE LEAFLET:  
INFORMATION FOR THE USER**

**Asacol® 800mg MR tablets**  
(mesalazine)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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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**1. What Asacol 800mg MR tablets are and what they are used for**

Asacol 800mg 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 800mg 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 800mg MR tablets act locally in the terminal ileum and colon to control the disease and prevent further flares of Crohn's ileo-colitis.

**2. What you need to know before you take Asacol 800mg MR tablets**

**Do not take the Asacol 800mg MR tablets if you:**

- are allergic to any of the ingredients in the product (see Section 6).
- are allergic to aspirin or any other salicylate medicine.
- had kidney problems or blood problems while taking other medicines such as sulphasalazine.
- have confirmed severe kidney or liver problems.
- have stomach ulcers, with or without bleeding.

DO NOT give the tablets to children unless directed by a doctor.

## **Warnings and precautions**

Talk to your doctor before taking Asacol 800mg MR tablets if you have any medical conditions or illnesses. Tell your doctor if you have:

- ever had any problems with your liver or kidneys, especially if you are elderly.
- suffered an allergy to the medicine sulfasalazine in the past.
- ever had allergic reactions of your heart such as inflammation of the heart muscle or heart sac. If you have had previous allergic reactions of your heart from mesalazine, then do not take Asacol 800mg MR tablets. Asacol 800mg MR tablets can be taken with care if you have had a previous allergic reaction of the heart even if not caused by taking mesalazine.
- ever developed a severe skin rash or skin peeling, blistering and/or mouth ulcers after using mesalazine
- if you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears contact your doctor immediately.

Serious skin reactions have been seen with mesalazine treatment. If you notice any symptoms of a skin reaction (listed in Section 4), stop taking Asacol and seek medical help immediately.

Asacol can cause red-brown urine in the toilet water. The colour change happens because of a reaction between mesalazine and bleach, but it doesn't harm you.

## **Taking other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription (over-the-counter).

Tell your doctor if you use any of the following:

- medicines that affect the immune system such as azathioprine, 6-mercaptopurine or thioguanine
- medicines that prevent the formation of blood clots, such as warfarin.

Asacol 800mg MR tablets should NOT be taken with **Lactulose**, a medicine for constipation.

Certain medicines can increase the risk of kidney reactions. These include:

- non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, aspirin, or naproxen.
- azathioprine, a medicine that weakens the immune system.

## **Pregnancy and breast-feeding**

Women who are pregnant or breast-feeding should not take Asacol 800mg 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 800mg 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.

Kidney stones may develop with use of mesalazine. Kidney stones are hard lumps that can cause pain in your sides and blood in your urine. Take care to drink enough liquid during treatment with mesalazine. This can help prevent kidney stones from developing.

### **Driving and using machines**

Asacol 800mg MR tablets are not expected to affect your ability to drive or operate machinery.

### **Important information about some of the ingredients of Asacol 800mg MR tablets**

- Lactose (a type of sugar contained in milk). This medicine contains a small amount of lactose. If you know you have an intolerance to some sugars, contact your doctor before taking this medicine.
- Sodium (salt). This medicine contains less than 1 mmol (23 mg) sodium per dosage unit, i.e. is essentially “sodium-free”.

### **3. How to take Asacol 800mg MR tablets**

Always take Asacol 800mg 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 the tablet. You can take them at any time of the day, with or without meals.

While taking this medicine, make sure you drink enough fluids to stay hydrated. This is especially important if you have been vomiting, having diarrhoea, have a high fever or heavy sweating. This will help avoid problems with your kidneys.

Recommended dose:

- Treating ulcerative colitis – up to 6 tablets each day divided throughout the day (as advised by your doctor).
- Preventing a flare of ulcerative colitis - up to 3 tablets each day once daily or divided throughout the day (as advised by your doctor).
- Preventing a flare of Crohn’s ileo-colitis - up to 3 tablets each day divided throughout the day (as advised by your doctor).

DO NOT take more than 6 tablets a day.

Asacol 800mg MR tablets are not recommended for use in children.

### **If you stop taking Asacol 800mg MR tablets**

Keep taking the 800mg MR 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 800mg MR tablets than you should**

Do not take more than 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 800mg 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 two doses together. 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 800mg MR tablets can cause side effects, although not everybody gets them.

A drug allergy is a reaction your body has to a medicine. Allergic reactions can happen after taking Asacol. **Tell your doctor** if you have any of these symptoms:

- Rash with or without itching,
- Shortness of breath,
- Rapid heartbeat,
- Chest pain.

These effects will usually disappear when you stop taking the medicine.

**Tell your doctor immediately** if you have any of the following:

- Fever, sore throat, mouth or lip ulcers, spots underneath the skin anywhere on your body, including the genital and anal area
- Become very pale
- Swollen ankles
- Have unusual bleeding (such as unexpected nosebleeds or bleeding gums)
- Skin rash with flaking, boils or sore lips or mouth
- Bruising more easily or blood problems
- Problems with how the kidney works, such as a change in the colour or amount of urine produced and swollen limbs or a sudden flank pain (caused by a kidney stone)
- Symptoms such as cramping, severe stomach pain, bloody and excessive stools (diarrhoea), fever, headache or rash.

These symptoms could be a sign of Acute Intolerance Syndrome. It can happen during a sudden episode of ulcerative colitis. This is a serious and rare condition and would require you to stop treatment immediately.

- If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears. These could be symptoms of increased pressure within your skull (idiopathic intracranial hypertension).

**Stop using mesalazine and seek medical attention immediately if you notice any of the following symptoms of a serious skin rash:**

- Reddish patches on the body that look like targets or circles. These patches might have blisters in the middle and your skin could peel. You may also have ulcers in your mouth, throat, nose, genitals and eyes. This rash can spread all over your body and you might have a fever and other flu-like symptoms (body aches, tiredness).

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

- Diarrhoea
- Stomach pain
- Vomiting
- Nausea (feeling sick)
- Wind
- Headache
- Joint and muscle pain
- Indigestion
- Rectal disorder (issues around the rectum, the part of the body where stool is held and then leaves the body).

**Rare side effects** (*may affect less than 1 in 1,000 people*):

- Problems with heart (including inflammation of the heart muscles and associated structures)
- Problems with liver (including inflammation of liver, liver failure, or abnormal liver tests)
- Problems with lung [including eosinophilic pneumonia (a lung disease where certain white blood cells increase in the lungs and bloodstream), bronchospasm (breathing difficulty caused by narrowed airways), unexplained wheezing or shortness of breath]
- Problems with kidney [including inflammation, scarring, or kidney failure, (which may go away if treatment is stopped early)]
- Inflammation of the pancreas, an organ involved in digestion
- Problems with blood (including a decrease in the number of white blood cells (help fight infection), red blood cells (carry oxygen to the body) and/or platelets (help stop bleeding))
- Numbness and tingling of the fingers and toes caused by nerve damage,
- Feeling dizzy or experiencing a spinning sensation (vertigo)
- Chest pain or chest infections
- Sinusitis (inflammation of the sinuses, which can cause pain and pressure in the face)
- Rhinitis (inflammation of the lining of the nose, which can cause a runny or stuffy nose)
- Skin rashes
- Skin blisters filled with fluid.
- Hair loss
- Cough
- Drug fever (having a fever while taking the medicine, which goes away when the medicine is stopped)
- Flu like symptoms such as body aches and tiredness
- Lupus, a long-term disease that can cause swelling and pain in any part of the body.

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

- Symptoms of colitis get worse
- Erythema multiforme (skin disorder that can cause redness and rashes).
- Lung scarring (tissue in the lungs becomes thick and stiff, making it hard to breathe)
- Temporary decrease in sperm count that returns to normal when the medicine is stopped

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

- Allergic reactions
- Constipation

- Lung disease (allergic reactions and diseases which can cause difficulty breathing, chest pain, and dry cough)
- Kidney stones and pain in your sides (see also Section 2).
- Increased pressure within your skull (idiopathic intracranial hypertension), symptoms of which could be strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears.
- Serious illness with blistering of the skin. These blisters can lead to skin peeling and result in painful, raw areas. This condition can also affect your mouth, eyes and genitals.
- Issues tolerating mesalazine. This can make your existing condition worse, causing severe diarrhoea and abdominal pain.

### **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 the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 800MG MR TABLETS**

Keep out of the sight and reach of children.

Please keep the moisture absorbing pouch in 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 800mg 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 in wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer need. This will help protect the environment.

## **6. Contents of the pack and other information**

### **What Asacol 800mg MR tablets contain**

The **active** substance is mesalazine. Each tablet contains 800 mg of mesalazine.

- Other ingredients inside the medicine core: lactose monohydrate (see Section 2), sodium starch glycolate, talc, povidone, magnesium stearate, colloidal anhydrous silica.
- Ingredients that coat the tablet: methacrylic acid-methyl methacrylate copolymer (1:2), talc, dibutyl sebacate, ferric oxide red (E172), methacrylic acid – methyl methacrylate copolymer (1:1), ferric oxide yellow (E172), macrogol.
- Ingredients to label the medicine: propylene glycol, ferric oxide black (E172), ammonium hydroxide, shellac.

### **What Asacol 800mg MR tablets look like and contents of the pack**

Asacol 800mg MR tablets are red-brown, coated, and oblong shaped, marked with WC 800. They are packed in a plastic bottle with a child-resistant closure that contains cotton/silica gel moisture absorbing pouches. Asacol 800mg MR tablets are available in packs of 12, 36, 84 or 180 tablets (not all pack sizes may be marketed).

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**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, 1 Bishops Square (Helios Court), Hatfield Business Park, Hatfield, AL10 9NE

Telephone Information Line:

01727 830038 Monday-Friday: 9am-5pm (except English bank holidays)

Crohn's and Colitis Support Line:

0300 222 5700 Monday-Friday: 9am-5pm (except English bank holidays)

To listen to or request a copy of this leaflet in Braille, large print or audio, please contact the Marketing Authorisation Holder.

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