PACKAGE LEAFLET: INFORMATION FOR THE USER

Asacolon 800 mg Gastro-resistant 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, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Asacolon is and what it is used for
2. What you need to know before you take Asacolon
3. How to take Asacolon
4. Possible side effects
5. How to store Asacolon
6. Contents of the pack and other information

1. What Asacolon is and what it is used for

The name of your medicine is Asacolon 800 mg Gastro-resistant Tablets. The tablets are called gastro-resistant tablets because they are covered with a coating which allows the tablets to pass through the stomach without dissolving. The tablet coating will break down in the bowel where the active mesalazine is released.

Asacolon Gastro-resistant Tablets contain the active substance mesalazine. This is an anti- inflammatory medicine used to treat ulcerative colitis and to prevent further episodes of Crohn's disease.

- Ulcerative colitis is a disease in which the lining of the large bowel (colon) or back passage (rectum) becomes inflamed (red and swollen). Asacolon acts locally at the inflamed sites to reduce the inflammation. It can also be used to prevent further attacks of ulcerative colitis.

- Crohn's disease is a disease in which the lining of the small and large bowel is affected and becomes inflamed. If you have been treated by surgery for Crohn's disease and it is under control, Asacolon acts to prevent further episodes of Crohn's disease.

2. What you need to know before you take Asacolon

DO NOT take Asacolon
- If you are allergic to mesalazine or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to salicylates (e.g. aspirin).
- If you have severe kidney impairment.
- If you have severe liver impairment.

This medicine is not indicated in children under the age of 2 years.

Warnings and precautions
Talk to your doctor before taking Asacolon if you have any medical conditions or illnesses, particularly if you have:
- any lung disease problems, e.g. asthma.
- liver disease.
- kidney disease.
- suffered an allergy to sulphasalazine 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 suspected mesalazine-induced allergic reactions of your heart, then Asacolon must not be taken. Asacolon can be taken with care if you have had a previous allergic reaction of the heart not caused by mesalazine.
- Blood dyscrasia, a condition in which different constituents of blood, such as white blood or red blood cells and platelets, are either high or too low in counts.
- ever developed a severe skin rash or skin peeling, blistering and/or mouth sores 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 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.

If you have an ulcer of the stomach or intestine, you should take Asacolon with care.

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

Mesalazine 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.

Test for your liver, kidney and blood
As a guideline, follow-up tests are recommended 14 days after commencement of treatment and then every 4 weeks for the following 12 weeks. If the findings are normal, follow-up tests should be carried out every three months. If additional signs appear, these tests should be performed immediately.

There have been a few reports of intact tablets in the stool. What appear to be intact tablets may sometimes be the remains of the tablet coating. If you often observe tablets or tablet shells in the stool, you should consult your doctor.

Children and adolescents
Asacolon is only recommended for use in children 6 years and older.

Other medicines and Asacolon
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines such as:
- Medicines that reduce the activity of the immune system (e.g. azathioprine, or 6-mercaptopurine, or thioguanine)
- Medicines that prevent the formation of blood clots (anticoagulants, e.g. warfarin).

Asacolon with food, drink and alcohol
The consumption of food, drink and alcohol does not interfere with the use of Asacolon.

Pregnancy, breast-feeding and fertility
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
Asacolon has no or negligible influence on the ability to drive and use machines. However, if you are affected in any way do not drive or operate machinery.

Intolerance to carbohydrates
Asacolon contains milk sugar (e.g. lactose) and therefore patients who are intolerant to lactose should contact their doctor before taking this medicine. Patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take 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 Asacolon

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
Asacolon should be taken before meals. This medicine must be swallowed whole preferably with some liquid. Do not chew, crush or break the tablets before swallowing them.

The recommended dose is:
Adults (including older people)
To treat ulcerative colitis:
2400 mg mesalazine per day once daily or in divided doses. If required this can be increased to 4800 mg per day in divided doses. Above 2.4g: Take only in divided doses.

To prevent an episode of ulcerative colitis:
1200–2400 mg mesalazine per day, once daily or in divided doses.

To prevent an episode of Crohn's disease:
2400 mg per day, once daily or in divided doses.
These can be taken as various combinations of tablets, for example:
1200 mg = 3 x 400 mg tablets
1600 mg = 4 x 400 mg tablets or 2 x 800 mg tablets
2400 mg = 6 x 400 mg tablets or 3 x 800 mg tablets
4000 mg = 10 x 400 mg tablets or 5 x 800 mg tablets
4800 mg = 12 x 400 mg tablets or 6 x 800 mg tablets

Use in children and adolescents:
Asacolon is only recommended for use in children 6 years of age 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.

If you take more Asacolon than you should
If you take more Asacolon than you should or this medicine was consumed by a child, speak immediately with your doctor.

If you forget to take Asacolon
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 Asacolon
Do not stop taking Asacolon without talking to your doctor first even if you feel better. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side-effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Organ specific side effects affecting the heart, lungs, liver, kidneys, pancreas, skin and subcutaneous tissue have been reported.

Stop taking Asacolon immediately and seek urgent medical advice
If you develop unexplained bruising (without injury), bleeding under your skin, purple spots or patches under your skin, anaemia (feeling tired, weak and looking pale, especially on lips, nails and inside of eyelids), fever (high temperature), sore throat or unusual bleeding (e.g. nose bleeds), 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 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) (frequency not known [cannot be estimated from the available data]).

The following side effects have been reported at the approximate frequencies shown:
Common (may affect up to 1 in 10 people):
- rash.
- indigestion.

Uncommon (may affect up to 1 in 100 people):
- fever
- high number of white blood cells called eosinophil granulocytes.
- sensation of tingling, pricking and numbness.
- hives, itching skin.
- chest pain.

Rare (may affect up to 1 in 1000 people):
- 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.
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

Very rare (may affect up to 1 in 10'000 people):
- 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, cough, 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).
- muscle or joint pain
- hair loss.
- 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 (frequency cannot be estimated from the available data):
- 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 and associated kidney pain (see also section 2)
- intolerance to mesalazine sometimes with worsening symptoms of underlying disease
- weight loss.
- laboratory test results out of normal range.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Asacolon

Keep this medicine out of the sight and reach of children.

Store in the original package in order to protect from moisture.
Do not store above 25°C.

Do not take this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Asacolon contains
- The active substance is mesalazine. Each tablet contains 800 mg mesalazine.

- The other ingredients are:
  Tablet core
  - lactose monohydrate
  - sodium starch glycolate (Type A)
  - magnesium stearate
  - talc
  - povidone

  Tablet coat
  - methacrylic acid – methylmethacrylate copolymer (1:2)
  - talc
  - triethyl citrate
  - yellow and red iron oxides
  - macrogol 6000.

What Asacolon looks like and contents of the pack

Asacolon 800 mg Gastro-resistant Tablets are reddish to brownish oblong tablets with a glossy to matt finish.

Asacolon 800 mg Gastro-resistant Tablets come in blister strips of ten tablets, which are packed as 90 tablets per carton.

Parallel Product Authorisation holder
IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

Manufactured by
Haupt Pharma Wulfing GmbH, Bethelner Landstrasse, 18, D-31028 Gronau, Germany or Rottendorf Pharma GmbH, Ostenfelder Strasse 51 – 61, 59320 Ennigerloh, Germany or Tillotts Pharma GmbH, Warmbacher Str. 80, 79618 Rheinfeiden, Germany.

Repackaged by
Cast Healthcare Ltd, Unit E, The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK(NI).

In addition, you may wish to contact the National Association for Colitis and Crohn's Disease which offers information, advice and local support groups.
Irish Society for Colitis and Crohn's Disease Carmichael House, North Brunswick Street, DUBLIN 7.

Asacolon is a registered trademark of Tillots Pharma AG.

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