Package leaflet: Information for the patient

Galtasa 1500 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, ask your doctor, pharmacist or nurse.
- 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 any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Galtasa is and what it is used for
2. What you need to know before you take Galtasa
3. How to take Galtasa
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1. What Galtasa is and what it is used for

Galtasa gastro-resistant tablets contain 1500 mg of the active substance mesalazine (also known as 5-aminosalicylic acid), which belongs to a group of drugs called intestinal anti-inflammatory drugs.

Galtasa is indicated in adults for the treatment of ulcerative colitis, an inflammatory bowel disease. It is indicated both for acute episodes and for the prevention of acute episodes

2. What you need to know before you take Galtasa

Do not take Galtasa:
- if you are allergic to mesalazine or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to acetylsalicylic acid or any other salicylate.
- if you have severe kidney impairment and/or liver impairment.

Warnings and precautions
Talk to your doctor or pharmacist before you start taking Galtasa.

Before starting treatment with Galtasa, tell your doctor:
- if you are or want to become pregnant
- if you are nursing your child
- if you have liver or kidney problems
- if you suffer from any lung disease, for example, asthma
- if you have been allergic to sulfasalazine in the past
- if you have a medical condition that can make you prone to bleeding
- if you have previously had inflammation of the heart (which could be a consequence of an infection in the heart).
- if you have 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

In case of any allergic manifestation (e.g. rash, pruritus) or cramps, abdominal pain, severe headache and fever during the course of treatment, do not take more tablets and tell your doctor immediately.

Before and during treatment, your doctor may want to perform blood and urine tests on a regular basis to check the functioning of your liver, kidneys, blood and lungs.

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

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.

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.

Children and adolescents
The safety information of the use of this medicine in children and adolescents is limited.
Do not administer to children under 5 years.

Other medicines and Galtasa:
In general, you can continue treatment with other medicines while taking Galtasa. However, tell your doctor or pharmacist if you are taking, have recently taken or might have to take any other medicines, including medicines obtained without a prescription.

Galtasa can interact with some medications if they are given at the same time.

In particular:
- medicines to lower blood sugar (antidiabetics)
- medicines to lower blood pressure (antihypertensives/diuretics)
- medications for the treatment or prevention of gout attacks
- medicines that help with bowel movements (laxatives containing lactulose)
- medicines to prevent blood clotting (anticoagulants)
- medicines to reduce the activity of the immune system (e.g. azathioprine or 6-mercaptopurine or thioguanine)
- medicines to treat pain and inflammation (anti-inflammatories)

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.

There is limited experience with the use of mesalazine during pregnancy and breast-feeding. The newborn may develop allergic reactions after breast-feeding, e.g. diarrhoea. If the newborn develops diarrhoea, breast-feeding should be discontinued.

Women who are pregnant or breast-feeding should not take Galtasa unless advised otherwise by their doctor.

Driving and using machines
Galtasa have no or negligible influence on the ability to drive or use machines.

Galtasa contains sodium
This medicine contains 48 mg (or 2.08 mmol) of sodium (main component of cooking/table salt) in each gastro resistant tablet. This is equivalent to 2.4 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Galtasa

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you the duration of your treatment with this medicine. Do not stop treatment earlier, even if you feel better, because the symptoms may come back if you stop treatment too soon.

Follow the treatment strictly according to the instructions of your doctor, both in the acute inflammatory phase and in the maintenance time that you establish.

The recommended dose for adults is:

To treat an **acute episode of colitis**, your doctor will usually prescribe a dose between 1.5 grams (one 1500 mg tablet) and 4 grams (two 1500 mg tablet and one 1000 mg tablets) of mesalazine per day, which can be given once daily or in divided doses.

To help **prevent more episodes**, your doctor may prescribe a dose between 1.5 grams (one 1500 mg tablet) and 3 grams (two 1500 mg tablet) of mesalazine per day, which can be given once daily or in divided doses.

Your doctor might prescribe different strengths available of Galtasa gastro-resistant tablets to adjust the dose.

Galtasa gastro-resistant tablets should be taken orally.
The tablets should be swallowed whole, with liquid and in the fasting state. Do not divide, chew or crush.

Use in children and adolescents
Galtasa is not recommended to be given to children and adolescents under 18 years of age due to lack of data on safety and efficacy. Do not administer to children under 5 years.

Use in elderly
The use of Galtasa in elderly patients should be done with caution and always limited to those patients with normal renal function.

If you take more Galtasa than you should
If you take more Galtasa than you should, contact your doctor, pharmacist or the hospital emergency department immediately. Take Galtasa package with you.

If you forget to take Galtasa
Do not take a double dose to make up for a forgotten dose.

If you stop taking Galtasa
It is important that you take Galtasa tablets every day, even when you do not have symptoms of ulcerative colitis. Always finish the treatment you have been prescribed.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines may cause allergic reactions although serious allergic reactions are very rare. If you get any of these symptoms after using this medicine, stop taking these tablets and contact your doctor immediately:
- allergic skin rash,
- fever,
- difficulty in breathing.

If you experience fever or irritation of the throat or mouth, stop using these tablets and contact your doctor immediately. These symptoms may be due very rarely to a reduction in the number of white cells in the blood (a condition called agranulocytosis).

Serious side effects:
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 (frequency not known [cannot be estimated from the available data]).

-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 also been reported in patients using mesalazine:

Rare (may affect up to 1 in 1 000 people):
- abdominal pain, diarrhoea, flatulence, nausea and vomiting;
- headache, dizziness;
- chest pain, shortness of breath or swollen limbs due to an effect on the heart;
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

Very rare: (may affect up to 1 in 10 000 people):
- problems with kidney function, sometimes with swollen limbs or flank pain;
- severe abdominal pain because of acute inflammation of the pancreas;
- worsening of colitis symptoms;
- fever, sore throat or feeling sick due to changes in blood count;
- shortness of breath, cough, wheezing, spot in the lungs x-ray due to allergic and/or inflammatory conditions in the lungs;
- diarrhoea and severe abdominal pain due to an allergic reaction to medicine at the bowel level;
- skin rash or inflammation;
- muscle and joint pain;
- jaundice or abdominal pain, due to liver or bile flow disorders;
- hair loss and development of baldness;
- erythema multiforme;
- numbness and tingling of the fingers and toes (peripheral neuropathy);
- reversible decrease in semen production;
- blood count disorders.

Unknown frequency (it cannot be estimated from the available data):
- kidney stones and associated kidney pain (see also section 2);

- severe cutaneous adverse reactions: Drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).

Photosensitivity
More severe reactions have been reported in patients with pre-existing skin conditions, such as atopic dermatitis and atopic eczema.

If these symptoms continue or become more severe, check with your doctor.

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

5. How to store Galtasa

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

This medicine does not require any special storage conditions.

Do not use 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 protect the environment.

6. Contents of the pack and other information

What Galtasa contains

- The active substance is mesalazine. Each gastro-resistant tablet contains 1500 mg of mesalazine
- The other ingredients are anhydrous sodium carbonate, glycine, povidone, silicified microcrystalline cellulose, croscarmellose sodium, silica, colloidal anhydrous, calcium stearate, methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent, methacrylic acid - methyl methacrylate copolymer (1:1), methacrylic acid - methyl methacrylate copolymer(1:2), sebacate, talc, titanium dioxide (E-171), macrogol and red iron oxide (E-172).

What Galtasa looks like and contents of the pack
Galtasa are oval, biconvex tablets, with homogeneus reddish coating.
This medicine is marketed in PVC/PVDC-Aluminium blisters packed in cartons containing 36, 60 or 96 gastro-resistant tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicine is authorised in the Member States of the European Economic Area under the following names:

Spain: Mecolvix 1500 mg comprimidos gastrorresistentes
Austria: Azzavix 1500 mg magensaftresistente tabletten
Ireland: Galtasa 1500 mg gastro-resistant tablets
Slovakia: Salcrozine 1500 mg gastrorezistentná tableta
Czechia: Salcrozine
Greece: Mecolzin

This leaflet was last revised in {**MM/YYYY**}.