

## **Package leaflet: Information for the patient**

### **Galtasa 500 mg suppositories** 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
4. Possible side effects
5. How to store Galtasa
6. Contents of the pack and other information

#### **1. What Galtasa is and what it is used for**

Galtasa contains the active substance mesalazine, which is an anti-inflammatory agent for the treatment of Ulcerative Colitis in adults.

Galtasa is indicated for:

- Distal Ulcerative Colitis (proctitis), an inflammatory disease of the last part of the colon e.g. rectum (back passage).
  - Treatment of mild or moderate acute exacerbations;
  - Maintenance of remission.

#### **2. What you need to know before you use Galtasa**

##### **Do not use 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 using Galtasa.

- 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 an ulcer in your stomach or bowel intestine
- 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.

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 use more suppositories 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 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 of age.

### **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 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)
- mesalazine may delay the excretion of methotrexate.

### **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.

## **3. How to use Galtasa**

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

Your doctor may adjust the dose, depending on your characteristics and on the characteristics of your disease. The recommended dose in adults is:

- Treatment of acute phase: one suppository twice or thrice daily (corresponding to a daily dose of 1000-1500 mg of mesalazine).
- Maintenance of remission: one suppository once or twice daily (corresponding to a daily dose 500-1000 mg of mesalazine).

Method of administration:

This medicine may only be used rectally, so it has to be inserted through the anus. Do NOT take by mouth.

It is recommended go to the toilet and empty your bowel before using the suppository.

It is advisable to introduce the suppository while you are lying on the left side and to remain in this position for about 1 hour.

Suppositories should be introduced deeply into the anus and should be retained in the rectum for 1-3 hours to increase the efficacy.

#### **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 use more Galtasa than you should**

If you use more Galtasa than you should, contact your doctor, hospital or emergency care, to get an opinion of the risk and advice on the action to be taken. Take the suppositories pack with you.

#### **If you forget to use Galtasa**

Do not use a double dose to make up for a forgotten dose.

It is important to use Galtasa suppositories every day, even when you do not have symptoms of ulcerative colitis. Continue the treatment as prescribed by your doctor.

#### **If you stop taking Galtasa**

Do not stop the treatment without first talking with your doctor.

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 suppositories 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 suppositories 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.

The following side effects have also been reported in patients using mesalazine:

**Rare side effects (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 side effects (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 upon 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.

**Adverse effects of unknown frequency (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).
- hypereosinophilia.

**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 or pharmacist. 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](http://www.hpra.ie).

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

**5. How to store Galtasa**

Do not store above 30°C. Do not refrigerate or freeze.

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

Do not use this medicine after the expiry date which is stated on the carton and strip 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 suppository contains 500 mg of mesalazine.
- The other ingredient is hard fat.

### **What Galtasa looks like and contents of the pack**

Galtasa is a torpedo-shaped suppository with greyish-white to slightly violet-reddish colour. Galtasa is available in strips of 12, 24, 30, 60 or 100 suppositories. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Faes Farma, S.A.  
Máximo Aguirre, 14  
48940 Leioa (Bizkaia)  
Spain

### **Manufacturer**

Faes Farma Portugal, S.A.  
Rua Elias Garcia, 28 2700-327 Amadora  
Portugal

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

Spain: Mecolnix 500 mg supositorios  
France: Kintasa 500 mg suppositoires  
Ireland: Galtasa 500 mg suppositories  
Romania: Azzavix 500 mg supozitoare  
Czech Republic : Salcrozine  
Hungary: Salcrozine 500 mg végbélkúp

**This leaflet was last revised in 01/2023.**