package leaflet: information for the patient

Gertac 150 mg and 300 mg Film-coated Tablets

ranitidine

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 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 or pharmacist. this includes any possible side effects not listed in this leaflet. see section 4.

what is in this leaflet
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2. what you need to know before you take Gertac
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1. What Gertac is and what it is used for
Gertac contains the active ingredient ranitidine, which belongs to a group of medicines called H₂ antagonists. These medicines work by reducing the amount of acid produced by the stomach.

Gertac is used in adults and children (aged 3 to 18 years) to treat duodenal ulcers, stomach (gastric) ulcers and heartburn or indigestion caused by a backwash of acid from the stomach (reflux oesophagitis).

This medicine is also used in adults to prevent duodenal ulcers occurring and to treat a rare condition known as Zollinger-Ellison syndrome.

2. What you need to know before you take Gertac
Do not take Gertac:
- if you are allergic to ranitidine or any of the other ingredients of this medicine (listed in section 6)
- if you have a rare inherited condition called porphyria

Warnings and precautions
Talk to your doctor or pharmacist before taking Gertac
- if you have problems with your kidneys
- if you are elderly
Gertac may hide the symptoms of other diseases. Before starting ranitidine treatment your doctor may carry out tests to confirm your condition and/or exclude other diseases.

If you are elderly, have chronic lung disease, diabetes or a weak immune system you may be at greater risk of catching pneumonia.

**Other medicines and Gertac**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, especially any of the following medicines:

- propranolol, procainamide or n-acetylprocainamide, for heart problems
- Non-Steroidal Anti-Inflammatory (NSAID) medicines, for pain and inflammation (e.g. ibuprofen, diclofenac)
- lidocaine, a local anesthetic
- diazepam, for worry or anxiety
- phenytoin for epilepsy
- theophylline, for breathing problems (asthma)
- warfarin or coumarin, for thinning the blood (ranitidine may change the effect of these drugs and increase or reduce the blood clotting time)
- glipizide, for lowering blood glucose
- atazanavir or delviridine, for treating HIV infection
- triazolam, for insomnia
- gefitinib, for lung cancer
- ketoconazole, an anti fungal medicine, sometimes used for treating thrush
- high doses of sucralfate (2g), a medicine used to help treat stomach and intestine problems such as reflux and ulcers. You should take Gertac 2 hours before or after the sucralfate.
- midazolam is a medicine that may be given to you just before you have an operation. Tell your doctor if you are taking Gertac before your operation in case he or she wants to give you midazolam.

**Pregnancy and breast-feeding**
Gertac can enter the baby’s blood if taken when you are pregnant and is found in human breast milk if taken when you are breast-feeding. Gertac should only be taken when you are pregnant or breast-feeding if it is absolutely necessary.
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**
This medicine is not expected to affect your ability to drive or use machines, however if you get any side effects such as dizziness, confusion or seeing, feeling or hearing things that are not there (hallucinations), speak to your doctor before attempting such activities.

**3. How to take Gertac**
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
You should swallow the tablets whole with water.

**Adults and children aged 12 years and over**

**Duodenal and gastric ulcers and reflux oesophagitis**
The recommended dose is 150 mg twice a day or 300 mg once a day after dinner or at bedtime. Depending on your response to treatment your doctor may increase your dose to 300 mg twice a day.

You should feel the benefit of your medicine quickly, however treatment should last for at least 4 weeks and your doctor may recommend you continue taking your tablets for up to 12 weeks.

**Prevention of duodenal ulcers**
The recommended dose is 150 mg or 300 mg once a day after dinner or at bedtime.

**Zollinger-Ellison syndrome**
The recommended dose is one 150 mg tablet three or four times a day, however, your doctor may increase this dose further.

**Children aged 3 to 11 years**
Your doctor will tell you how much medicine should be given, based on the weight of your child and the condition being treated. This medicine should be given exactly as your doctor tells you.

For the treatment of ulcers, the recommended dose is 2 mg for every kg of the child’s body weight, given twice each day for 4 weeks or in some cases up to 8 weeks. Your doctor may increase this to 4 mg for every kg of weight, to a maximum total of 300 mg each day.

For the treatment of reflux oesophagitis, the recommended dose is 2.5 mg for every kg of the child’s body weight, given twice each day. Your doctor may increase this to 5 mg for each kg of weight, to a maximum total of 600 mg each day.

Depending on the weight of your child these tablets may not be suitable. In order to be able to give your child the correct dose, your doctor may choose a more appropriate form of this medicine. Speak to your doctor or pharmacist if you are not sure.

**Kidney problems**
If you have kidney problems your doctor may change your dosage.

**If you take more Gertac than you should**
It is important to take your tablets according to the instructions on the label. If you take too many tablets contact your doctor or hospital for advice.

**If you forget to take Gertac**
If you forget to take your tablets take them as soon as you remember unless it is almost time to take the next dose. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, stop taking Gertac and tell your doctor immediately or go to your nearest hospital emergency department:

**Rare: may affect up to 1 in 1,000 people**
- Signs of an allergic reaction, which may include swelling or rash on the lips, tongue or face, feeling dizzy, fever, chest or throat pain, difficulty breathing or low blood pressure

**Very rare: may affect up to 1 in 10,000 people**
- Serious skin reactions, which may include red, itchy, swollen or peeling skin with blisters or severe skin rash.
- Inflammation of the pancreas, causing severe stomach pain that can spread to the back
- Inflammation of the membranes around the brain and spinal cord (meningitis), which may cause fever, feeling or being sick, headache, stiff neck and sensitivity to bright light. This form of meningitis does not pass on to other people
- Inflammation of the liver (hepatitis), which may cause yellowing of the skin and whites of the eyes, loss of appetite, fever, feeling generally unwell, pale stools or dark urine
- Problems with your heart causing an irregular, faster or slower than usual heart beat or ‘missed’ beats
- Changes to the number of cells in your blood that may cause you to feel more tired than usual or have pale skin (fewer red blood cells), have more frequent infections with fever, chills, sore throat or mouth ulcers (fewer white blood cells), or to bleed or bruise more easily or for longer than usual (fewer platelets).

**Other possible side effects**

**Very common: may affect more than 1 in 10 people**
- Severely injured patients are more likely to suffer infectious complications if taking ranitidine compared with sucralfate.

**Uncommon: may affect up to 1 in 100 people**
- Feeling and being sick, stomach cramp and pain, diarrhoea and constipation

**Rare: may affect up to 1 in 1,000 people**
- Change in liver or kidney function, these will show up on a blood test
- Skin rash

**Very rare: may affect up to 1 in 10,000 people**
- Feeling low or sad (depression), seeing or hearing things that are not there (hallucinations) or confusion
- Sometimes severe headache, dizziness, uncontrolled movement or blurred vision
- Inflammation of blood vessels often with skin rash
- Hair loss
- Joint or muscle pain
- Kidney inflammation (which can cause back pain and make you feel generally unwell)
- Loss of libido inability to get or maintain an erection, swelling of the breasts in men (gynaecomastia) or unexpected production of milk in women
- Sensitivity of the skin to light

**Not known: frequency cannot be estimated from the available data**
Shortness of breath

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 Earlsfort Terrace, IRL – Dublin 2; Tel +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gertac

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 blister, label or carton after EXP. The expiry date refers to the last day of that month

Do not store above 25°C and keep the tablets in the original package in order to protect from light.

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 Gertac contains

- The active substance is ranitidine hydrochloride. Each film-coated tablet contains ranitidine hydrochloride equivalent to 150 mg or 300 mg of ranitidine.
  - The other ingredients in the tablet core are microcrystalline cellulose and magnesium stearate. The 300 mg tablets also contain croscarmellose sodium.
  - The film coating contains hypromellose, titanium dioxide, polydextrose, triethyl citrate and macrogol.

What Gertac looks like and contents of the pack

The 150 mg tablets are white to beige film-coated round tablets with ‘G’ on one side and ‘00’ over ‘30’ on the reverse
The 300 mg tablets are white to beige film-coated capsule-shaped tablets with ‘G’ on one side and ‘0031’ on the reverse

This medicine is available in plastic bottles and blister packs containing: 10, 12, 14, 20, 28, 30, 50, 56, 60, 90 or 100 tablets. Not all pack sizes may be marketed.
Marketing Authorisation Holder
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This medicinal product is authorised in the member statues of the EEA under the following names:
Belgium: Ranitidine Mylan 150mg and 300mg;
Denmark: Ranitidin Mylan;
France: Ranitidine Mylan 150mg and 300mg;
Greece: Rantidine/Mylan TAB 150mg and 300mg;
Ireland: Gertac 150mg and 300mg;
Italy: Ranitidina Mylan Generics;
Luxembourg: Ranitidine Mylan 150mg and 300mg;
Portugal: Ranitidina Mylan 150mg and 300mg;
Spain: Rantidina Mylan 150mg and 300mg EFG

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