Package leaflet: Information for the user

Ranitidine 150 mg effervescent tablets
Ranitidine 300 mg effervescent tablets
ranitidine (as hydrochloride)

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:

1. What Ranitidine effervescent tablets are and what they are used for

Ranitidine is a gastrointestinal drug. It belongs to the group known as histamine H2 receptor blockers, which reduce the secretion of stomach acid.

For adults Ranitidine effervescent tablets are used for the treatment of diseases of the stomach and duodenum, in which a reduction of stomach acid is required:
- Intestinal ulcers;
- Benign stomach ulcers;
- Prevention of the return of stomach ulcers in patients with recurrent ulcers;
- Inflammation of the gullet as a result of the backflow of stomach contents (reflux oesophagitis);
- Zollinger-Ellison Syndrome (a disease whereby the stomach produces too much acid).

Ranitidine is **not** indicated for the treatment of mild stomach/ intestinal complaints, such as nervous stomach.

For children (3 to 18 years) Ranitidine effervescent tablets are used for:
- the short term treatment of stomach ulcers (ulcers in the part of the gut that connects to the duodenum)
- the treatment of inflammation of the gullet (the tube between your mouth and stomach) caused by too much stomach acid. This can cause pain or discomfort sometimes known as “indigestion”, “dyspepsia” or “heartburn”.

2. What you need to know before you take Ranitidine effervescent tablets

Do not take Ranitidine effervescent tablets:
- if you are allergic to ranitidine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Ranitidine effervescent tablets

- if you suffer from a reduced kidney function; a lower dose may be needed (see section 3: "How to take Ranitidine effervescent tablets")
- if you have a history of porphyria (a severe illness whose symptoms include severe stomach pain, mental confusion and muscle weakness)
- if you suffer from severe liver impairment; you should use this medicine with caution
- if you are elderly, if you have a chronic lung disease, diabetes or problems with your immune system, you may have an increased risk of developing community acquired pneumonia
- if you have mild, short-lasting stomach or intestinal complaints; ranitidine is indicated for patients with severe complaints and should not be used to treat mild complaints
- if you are taking painkillers such as non-steroidal anti-inflammatory medicines, especially if you had stomach ulcers before or if you are over 65 years old

Stomach and duodenal ulcers can be caused by a certain bacteria called *Helicobacter pylori*. Your doctor may therefore prescribe other medicines (antibiotics) that can kill these bacteria.

Before starting treatment with ranitidine, it is important that your doctor has established that your stomach/ duodenal ulcer is not malignant.

Ask your doctor if any of the above warnings apply to you, or has ever applied to you in the past.

Other medicines and Ranitidine effervescent tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

An interaction may occur if you take these effervescent tablets at the same time as:
- coumarin anticoagulants (e.g. warfarin, for thinning your blood)
- procainamide and N-acetylprocainamide (medicines for the treatment of cardiac arrhythmias)
- triazolam, midazolam (mood-enhancing drugs)
- glipizide (medicine for the treatment of diabetes)
- ketoconazole (medicine for the treatment of fungal infections)
- atazanavir, delaviridine (medicine for treatment of HIV infection)
- gefitinib (medicine for treatment of lung cancer)

If you are taking erlotinib, a drug used for the treatment of certain types of cancer, talk to your doctor before you take **Ranitidine effervescent tablets**. Ranitidine contained in **Ranitidine effervescent tablets** may decrease the amount of erlotinib in your blood and your doctor may need to adjust your treatment while you are receiving erlotinib.

You should always take medicines which reduce stomach acid (e.g. antacids, sucralfate) **2 hours after Ranitidine effervescent tablets**, in order to prevent a reduction in the efficacy of Ranitidine effervescent tablets.

Ranitidine effervescent tablets with alcohol
Ranitidine can increase the effect of alcohol.

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.

If you are pregnant, might become pregnant or are breast-feeding, you should not take this medicine unless your doctor advises it is essential.

Ranitidine passes into breast milk. Breast-feeding is therefore **not** recommended whilst using Ranitidine.

Driving and using machines

No effects on the ability to drive or operate machinery were reported when using ranitidine only. Ranitidine effervescent tablets can increase the effect of a small amount of alcohol. If you have drunk alcohol, do not drive and/or use machines that require you to be alert.

Ranitidine effervescent tablets contains lactose
If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine.

Ranitidine effervescent tablets contains sodium
Each Ranitidine 150 mg effervescent tablet contains 120 mg sodium (main component of cooking/table salt). This is equivalent to 6% of the recommended maximum daily dietary intake of sodium for an adult.
Talk to your doctor or pharmacist if you need 4 or more tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

Each Ranitidine 300 mg effervescent tablet contains 240 mg sodium main component of cooking/table salt). This is equivalent to 12% of the recommended maximum daily dietary intake of sodium for an adult.
Talk to your doctor or pharmacist if you need 2 or more tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take Ranitidine effervescent tablets

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

Dissolve the effervescent tablets without breaking them in a full glass of water. Wait until the tablets have dissolved and then drink the solution. You may take the tablets with or without a meal.

Unless otherwise prescribed by your doctor, the recommended dose is:

Dosage
Adults and adolescents (12 years and over) with normal kidney function:
Intestinal or benign stomach ulcer
2 x 150 mg effervescent tablets or 1 x 300 mg effervescent tablet a day, in a single dose after an evening meal or in the evening before bedtime; alternatively, in two doses, i.e. 150 mg at breakfast and 150 mg in the evening before bedtime. Treatment lasts for 4 weeks, but can be extended to 8 weeks.

Prevention of stomach ulcer relapse (150 mg strength only)
1 x 150 mg effervescent tablet per day, in the evening before bedtime. Treatment lasts for 12 months or less, depending on the instructions of the doctor.

Inflammation of the gullet due to backflow of stomach acid
2 x 150 mg effervescent tablets or 1 x 300 mg effervescent tablet a day, in a single dose after an evening meal or in the evening before bedtime. Alternatively, these tablets may be taken in two doses, i.e. 150 mg at breakfast and 150 mg in the evening before bedtime. If necessary, dosage can be increased to 4 x 150 mg effervescent tablets or 2 x 300 mg effervescent tablets a day. Treatment lasts for 8 weeks, but can be extended to 12 weeks.

Patients with severe stomach acid secretion (e.g. caused by Zollinger-Ellison Syndrome)
Starting dose: 1 x 150 mg effervescent tablet three times a day. If necessary, dosage can be increased to 600 - 900 mg (4-6 x 150 mg effervescent tablets or 2-3 x 300 mg effervescent tablets) a day. Length of treatment: according to your doctor’s instructions.

Patients with reduced kidney function
Your dosage will be lowered by your doctor, depending on the extent to which your kidney function is impaired.

Patients with reduced liver function
Such patients can be treated at the usual dosage schedules.

Children over 30 kg of weight and from 3 to 11 years
Your doctor will work out the right dose for you based on your child's weight.

Treatment of stomach or duodenal (small intestine) ulcers
The usual dose is 2 mg for each kg of body weight, twice a day for four weeks. This dose may be increased to 4 mg for each kg, twice a day. Take each dose about 12 hours apart. The duration of treatment may be increased to 8 weeks.

Treatment of heartburn due to too much acid
The usual dose is 2.5 mg for each kg of body weight, twice a day for two weeks. The dose may be increased to 5 mg for each kg, twice a day. Take each dose about 12 hours apart.

If you take more Ranitidine effervescent tablets than you should
If you have taken more than the prescribed dose, you must contact your doctor or pharmacist immediately.

If you forget to take Ranitidine effervescent tablets
If you have forgotten a dose, take it as soon as you remember. If it is nearly time for your next dose, skip the forgotten dose and carry on as normal. Do not take a double dose to make up for the forgotten dose. You should check with your doctor or pharmacist if you are not sure.

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.

Serious side effects
A few people can be allergic to some medicines. These reactions can occur following administration of a single dose. If any of the following side effects come on soon after taking these tablets, stop the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:
- hives, swelling of tongue, lips, face and throat (angioedema), fever, constriction of the airways, drop in blood pressure, inadequate blood flow through the body (circulatory shock), chest pain.
  These side effects occur rarely (may affect up to 1 in 1,000 people).

Other possible side effects
Uncommon (may affect up to 1 in 100 people)
- tiredness
- abdominal pain, diarrhoea, constipation, feeling sick (these symptoms mostly improved during continued treatment)

Rare (may affect up to 1 in 1,000 people)
- a slight rise in one laboratory value (serum creatinine) (usually slight; normalised during continued treatment)
- hypersensitivity reactions e. g. urticaria (reddening of the skin with itching), angioneurotic oedema (serious allergic reaction which causes swelling of the face or throat), fever, bronchospasm (difficulty in breathing or wheezing), low blood pressure and chest pain

- transient and reversible changes in liver function tests
- skin rash, itching

Very rare (may affect up to 1 in 10,000 people)
- there can be changes in the level of certain substances in your blood (leucopenia, thrombocytopenia, agranulocytosis, pancytopenia). This can lead to you feeling unusually tired or short of breath and being more likely to bruise or get an infection.
- anaphylactic shock (serious allergic reaction which causes difficulty in breathing or dizziness). This event has been reported after a single dose)
- reversible mental confusion, depression and hallucinations. These have been reported predominantly in severely ill patients, elderly patients and patients with kidney disease.
- headache (sometimes severe), dizziness and reversible involuntary movement disorders.
- reversible blurred vision. There have been reports of blurred vision, which is suggestive of a change in accommodation.
- as with other H2 receptor antagonists tachycardia (increased heart rate), bradycardia (slower heart beat) and AV block (disturbances in the conduction [flow] of electrical impulses passing from the upper to the lower chambers of the heart).
- vasculitis (your small blood vessels can become swollen, often with skin rash)
- acute pancreatitis (inflammation of the pancreas, which causes severe pain in the abdomen and back)
- an inflammation of the liver due to a virus or other insult to the liver (hepatitis) with or without jaundice, these were usually reversible
- a particular form of skin rash (Erythema multiforme)
- hair loss
- your joints or muscles are painful or swollen or you cannot control their movement (arthralgia and myalgia)
- inflammation of the kidneys (acute interstitial nephritis)
- reversible impotence, breast symptoms and breast conditions (such as gynaecomastia and galactorrhoea)

Not known (frequency cannot be estimated from the available data)
- pneumonia (inflammation of the lung, see section 2. “Warnings and precautions”)
- dyspnoea (difficulties to breathe)

Paediatric population
The safety of ranitidine has been assessed in children aged 0 to 16 years with acid-related disease and was generally well tolerated with an adverse event profile resembling that in adults. There are limited long term safety data available, in particular regarding growth and development.

Reporting of side effects
If you get 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 Yellow Card Scheme at:
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 Ranitidine effervescent tablets

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 packaging after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.
Keep the tube tightly closed in order to protect from moisture.

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 Ranitidine effervescent tablets contains:
The active substance is ranitidine.

Each 150 mg effervescent tablet contains 150 mg ranitidine (as hydrochloride).
Each 300 mg effervescent tablet contains 300 mg ranitidine (as hydrochloride).

The other ingredients are tartaric acid, sodium hydrogen carbonate, lactose monohydrate, povidone, riboflavin sodium phosphate (E101), simethicone emulsion, sodium cyclamate, saccharine sodium, lemon aroma (contains citral, citronella oil, coriander oil, lime and arabic gum), macrogol 6000 and sodium hydroxide.

What Ranitidine effervescent tablets looks like and contents of the pack
Yellow-white to light-yellow cylindrical effervescent tablets with bevelled edges.

Ranitidine 150 mg effervescent tablets
Pack sizes: 10, 20, 30, 50, 60, 90 or 100 effervescent tablets.

Ranitidine 300 mg effervescent tablets
Pack sizes: 10, 20, 30, 50, or 100 effervescent tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
ratiopharm GmbH, Graf-Arco-Str. 3, D-89079 Ulm, Germany.

Manufacturer:
Merckle GmbH, Ludwig-Merckle-Strasse 3, 89143 Blaubeuren, Germany.

For any information about this medical product, please contact the local representative of the Marketing Authorisation Holder: ratiopharm UK Ltd, Cosham, Portsmouth, PO6 1UP

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