

Patient Information Leaflet

ZantacTM 75mg Film coated tablets *ranitidine (as hydrochloride)*

Please read all of this leaflet carefully before you start to take this medicine because it contains important information for you.
This medicine is available without prescription. However, you still need to take Zantac 75 tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 14 days.
- If any of the side effects get serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Zantac 75 tablets are and what they are used for
2. Before you take Zantac 75 tablets
3. How to take Zantac 75 tablets
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1. What Zantac 75 tablets are and what they are used for

Each tablet contains 75mg of ranitidine (as hydrochloride). Ranitidine belongs to a group of medicines known as histamine H2 antagonists. The stomach contains hydrochloric acid which helps to digest your food. Sometimes your stomach produces too much acid. This excess acid can lead to the conditions known as heartburn and dyspepsia (acid indigestion). Zantac 75 tablets are for the short-term relief of the symptoms of heartburn, excess acid and dyspepsia (acid indigestion).

2. Before you take Zantac 75 tablets

Do NOT take Zantac 75 tablets:

- if you are allergic to ranitidine or any of the other ingredients listed in Section 6.
- if you suffer from a rare condition called porphyria.

Take special care and consult your doctor before you take Zantac 75 tablets:

- if you are middle aged or older and have acid indigestion symptoms for the first time or symptoms that have recently changed.

- if you have been told you have a peptic ulcer ("stomach" or "duodenal").
- if you have unintended weight loss associated with dyspepsia.
- if you have kidney or liver problems.
- if you suffer from long-term lung disease, diabetes, are over 65 years or are unable to resist infection as you may be at increased risk of getting a serious chest infection (pneumonia); symptoms include fever, cough and breathlessness.
- if you have any other illness or you are under regular medical supervision.

Taking other medicines with Zantac 75 tablets:

If you are taking or have recently taken any other medicines, including other medicines obtained without a prescription tell your pharmacist or doctor before taking Zantac 75 tablets - especially:

- medicines to prevent blood clotting such as warfarin.
- pain-relievers of the class known as non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin or ibuprofen.
- medicines such as triazolam and midazolam (anxiety), glipizide (oral antidiabetic), ketoconazole (antifungal agent), atazanavir and delavirdine (antiviral agents) and gefitinib (anticancer agent).

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant, trying to become pregnant or breastfeeding.

Driving and using machines

Zantac 75 tablets has not been shown to affect your ability to drive or operate machinery.

3. How to take Zantac 75 tablets

Adults (including the elderly) and children 16 years of age and older:
Swallow one Zantac 75 tablet whole, with a drink of water, as soon as you have symptoms, at any time of the day or night.

Most people will find one or two tablets per day sufficient.
Do not take more than two tablets in 24 hours.

Do not take Zantac 75 tablets for more than 14 consecutive days without consulting your doctor or pharmacist.

Children under 16 years:

Do not give to children under 16 years of age.
Do not exceed the recommended dose.

If you take too many tablets:

If you accidentally take more tablets than recommended contact your doctor or pharmacist.

4. Possible side effects

Most people taking this medicine find that it causes no problems.
As with all medicines, allergic reactions may occur rarely.

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If you have any of the following symptoms soon after taking Zantac 75 tablets, STOP taking the tablets and tell your doctor immediately:

Possible side effects:

- allergic reaction: sudden wheeziness and chest pain or tightness, swelling of eyelids, face, lips, mouth or tongue, lumpy skin rash or "hives" anywhere on the body, unexplained fever, feeling faint, especially on standing up.
- severe stomach pain, this may be a sign of something called "pancreatitis".
- slow or irregular heartbeat.
- kidney problems (symptoms may include changes in the amount of urine passed and its colour, nausea, vomiting, confusion, fever and rash).

Uncommon (affects between 1 in 100 and 1 in 1,000 people):

- abdominal pain, constipation or nausea.

Rare (affects between 1 in 1,000 and 1 in 10,000 people)

- changes in tests which measure the function of your liver or kidneys, skin rash.

Very Rare (affects less than 1 in 10,000 people)

- anaphylactic shock, recurrent infection or unexpected bruising, confusion, depression or hallucinations, headache or dizziness, hair loss, abnormal muscular body movements or shaking, blurred vision, tiredness or fainting, inflammation of the blood vessels (vasculitis), diarrhoea. Hepatitis (inflammation/ infection of the liver, which may manifest as severe stomach pain or a change in the type of pain, nausea or vomiting and loss of appetite, which are worse than normal and/or jaundice (yellow colouring of the skin or the whites of the eyes)). Skin reaction, occasionally severe (red/purple spots or rash), joint or muscle pains. If you are a man - impotence, breast tenderness and/or breast enlargement or secretions from the breast.

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 on this label. You can also report side effects directly 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 Zantac 75 tablets

Store below 25°C.
Tablets should not be removed from blisters until immediately prior to use.

Keep out of the reach and sight of children.

Do not take the tablets after the expiry date (EXP) shown on the carton and tablet blister pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

The active ingredient is ranitidine 75mg (as hydrochloride).
The other ingredients are microcrystalline cellulose, magnesium stearate, hypromellose, titanium dioxide, triacetin and synthetic red iron oxide (E172).

Zantac tablets are pink, five sided film coated tablets with a "Z" engraved on one side and "75" on the other. Zantac tablets come in packs of 6, 12 or 24 tablets. Not all pack sizes may be marketed.

How can I avoid heartburn, excess acid and dyspepsia (acid indigestion)?

A number of factors may contribute towards people suffering heartburn, excess stomach acid and dyspepsia (acid indigestion): over eating, poor diet (too much fatty food), being overweight, lack of exercise, smoking and excessive alcohol intake.

If at all possible it is best to moderate your lifestyle where each of these factors is concerned to ensure you have the best possible chance of avoiding heartburn, excess stomach acid and dyspepsia (acid indigestion).

Not all the information about your medicine is printed here.

If, after reading this leaflet, you have any questions or are not sure about anything, ask your pharmacist.

YOU MAY WANT TO READ THIS LEAFLET AGAIN. PLEASE DO NOT THROW IT AWAY UNTIL YOU HAVE FINISHED YOUR MEDICINE.

Product Authorisation Holder is:

Chefaro Ireland DAC, Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland and all enquiries should be sent to this address.

Manufactured by:

Glaxo Wellcome SA, Aranda de Duero, Burgos, Spain or
Omega Pharma International, Venecoweg 26, B-9810 Nazareth, Belgium or
FAMAR ITALIA S.P.A. Via Zambeletti, 25 20021 Baranzate, Milano Italy.
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This leaflet was last revised in January 2017.
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