

**PACKAGE LEAFLET: INFORMATION FOR THE USER****Ranicalm® 75 mg Film- Coated Tablets**

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 6 days.

**In this leaflet:**

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other Information

**1. What this medicine is and what it is used for**

The active ingredient ranitidine belongs to a group of medicines called 'H2-blockers'. This medicine works by preventing your stomach from producing too much acid. This medicine treats indigestion and heartburn for up to 12 hours. One of the most common causes of indigestion and heartburn is excess acid in the stomach.

**2. What you need to know before you take this medicine**

**Do not take these tablets without consulting your doctor if you:**

- you are allergic to ranitidine or to any of the other ingredients of this medicine (listed in section 6)
- are under 16 years

**Warnings and precautions**

Talk to your doctor or pharmacist before taking your medicine if:

- you have **difficulty swallowing**
- you have a **porphyria** (too much of the pigment called porphyrin which may discolour the urine)
- you have **unintended weight loss**
- you are **middle-aged** or older with **new or recently changed indigestion** symptoms
- you have **persistent stomach pain**
- you have **kidney or liver problems**
- you are under **regular medical supervision**
- you have had a **peptic ulcer**
- you are **elderly**
- you have **breathing problems**
- you have a **weak immune system**
- you suffer from **diabetes**

**Other medicines and Ranicalm®**

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.**

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- non-steroidal Anti-Inflammatory (NSAID) medicines, for pain and inflammation e.g. ibuprofen or aspirin

- lidocaine, a local anaesthetic
- propranolol for heart problems
- glipizide, for lowering blood glucose
- diazepam, for worry or anxiety problems
- phenytoin, for epilepsy
- theophylline, for breathing problems (asthma)
- warfarin, for preventing blood clotting
- atazanavir or delaviridine, for treating HIV infection
- triazolam, or midazolam for insomnia
- gefitinib, for lung cancer
- ketoconazole, itraconazole or posaconazole, for fungal infections

This advice is even more important if you are elderly.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Ranicalm®.

**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 for advice before taking this medicine.

**3. How to take this medicine**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

**Adults (including elderly) and children 16 years of age and older:**

- Swallow one tablet whole with a drink of water as soon as you have the symptoms.
- If symptoms persist for more than one hour, take another tablet. Do not take more than two tablets in 24 hours.
- Do not use for more than 6 days.



- Do not buy a second packet of tablets without speaking to your doctor or pharmacist.
- Do not take more than the recommended dose.
- Do not give to children under 16 years of age.

#### If you take more of this medicine than you should

- Contact your nearest hospital casualty (A&E) or your doctor immediately.

#### 4. Possible side effects

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

**STOP TAKING** this medicine and tell your doctor immediately if you suffer from any of the following:

- Allergic reactions: These include developing an itchy rash, swelling of the eyelids, face or lips (with or without a lumpy skin rash elsewhere on the body), unexplained fever, anaphylactic shock the symptoms of which may include difficulty breathing, dizziness (especially on standing up) and chest pain or tightness.
- Unexplained bruising or bleeding, sore throat, mouth ulcers, fever, extreme paleness, weakness or exhaustion. These can be signs of blood disorders such as anaemia, low white blood cells, low platelet count, suppressed bone marrow or reduction in agranulocytes (a type of white blood cell).

The following side effects may occur. **Tell your doctor** if you get them:

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

- Confusion, depression or hallucinations
- Headache, dizziness or sudden, jerky movements
- Changes in heart rhythm
- Inflammation of your blood vessels
- Sudden inflammation of your pancreas (you may get severe stomach pain) or diarrhoea

- Inflammation of your liver which may cause one or more of the following: feeling or being sick, fever, itching, yellowing of the skin and eyes, dark coloured urine. This can cause changes to your liver function tests

- Hair loss, blurred vision
- Aches and pains in your muscles and joints
- Erythema multiforme (a severe form of rash with itchy pink-red blotches, which may blister)
- Sudden inflammation of your kidneys
- Impotence
- Swollen, tender or leaking breasts

#### Rare (affects up to 1 in 1,000 people)

- Skin rash
- Increase of serum creatine in the blood (kidney function test)
- Changes to liver function

#### Uncommon (affects less than 1 in 100 people)

- Stomach pain, constipation, feeling sick (nausea)

#### 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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store this medicine

- Keep this medicine out of the sight and reach of children
- Do not store above 25°C. Store in the original package.
- Do not use this medicine after the expiry date which is stated on the carton (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 Ranicalm® 75mg Tablet contains:

- Each tablet contains 75mg of the active substance, ranitidine hydrochloride.
- The other ingredients are: microcrystalline cellulose, magnesium stearate, hypromellose and titanium dioxide (E171).

##### What Ranicalm® 75mg Tablet looks like and contents of the pack

- Tablets are white to almost white, circular, biconvex, film coated tablets embossed with "BL" on one side and "75" on the other side.
- Ranicalm® 75mg tablets are available in packs of 6 and 12 tablets.

##### Marketing Authorisation Holder and Manufacturer

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##### Ranicalm® 75mg Film-Coated tablets, PL 17907/0028

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