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, nurse 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Ranitidine 150mg Tablets, Ranitidine 300mg Tablets but will be referred to as 'Ranitidine Tablets' throughout the remainder of this leaflet.

What is in this leaflet
1. What Ranitidine Tablets are and what they are used for
2. What you need to know before you take Ranitidine Tablets
3. How to take Ranitidine Tablets
4. Possible side effects
5. How to store Ranitidine Tablets
6. Contents of the pack and other information

1. WHAT RANITIDINE TABLETS ARE AND WHAT THEY ARE USED FOR

Ranitidine belongs to a group of medicines called H₂ antagonists, which reduce the amount of acid produced in your stomach.

For adults (including older people) Ranitidine is used to:
- heal and prevent ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- prevent stomach ulcers when they are a side effect of some medicines
- stop ulcers from bleeding
- improve problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as ‘indigestion’, ‘dyspepsia’ or ‘heartburn’
- stop acid coming up from the stomach while under anaesthetic during an operation.

For children (3 to 18 years) Ranitidine is used to:
- heal ulcers in the stomach, or the part of the gut empties into (the duodenum)
- heal and prevent problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as ‘indigestion’, ‘dyspepsia’ or ‘heartburn’.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RANITIDINE TABLETS

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

Warnings and precautions
Talk to your doctor, pharmacist, or nurse before taking Ranitidine Tablets if any of the below warnings apply to you or have ever applied in the past:
- your kidneys are not working properly
- you are pregnant or think you may be pregnant
- you are breast-feeding your baby
- you have a rare illness called porphyria
- you have had stomach ulcers before
- you are over 65 years old
- you have a current heart problem or a history of heart trouble
- you have a weak immune system
- you are diabetic
- you have stomach cancer
- you have any unintentional weight loss associated with acid indigestion
- you have lung disease.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before using this medicine.

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

In particular tell your doctor if you are taking:
- lidocaine, a local anaesthetic
- warfarin, used to thin the blood
- propranolol, procainamide or n-acetylprocainamide, for heart problems
- diazepam, for worry or anxiety problems
- phenytoin, for epilepsy
- theophylline, for breathing problems
- glipizide, used to lower blood glucose
- atazanavir or delavirdine, for treating HIV infection
- gefitinib for lung cancer
- ketoconazole for fungal infections or thrush
- triazolam or midazolam for insomnia. Midazolam may also be given before an operation. Tell your doctor you are taking ranitidine before you have an operation.

Pregnancy, breast-feeding and fertility
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.

Fertility
There is no data on the effects of ranitidine on human fertility. There were no effects on male and female fertility in animal studies.

Driving and using machines
Ranitidine Tablets may cause dizziness. You should not drive or operate machinery if you experience this effect. Talk to your doctor if this effect becomes worse.

3. HOW TO TAKE RANITIDINE TABLETS

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

Method of administration
- Take this medicine by mouth only.

Adults
For stomach or duodenal ulcers, adults usually take:
- 150mg twice a day in the morning and evening, or
- 300mg at bed time.

For stomach ulcers, adults usually take:
- 150mg twice a day in the morning and evening, or
- 300mg at bed time.

The doctor may change the dose.

You will normally have to take this medicine for between four and eight weeks depending on how quickly your condition clears up.

For inflammation of the gullet (oesophagitis) you may need to take this medicine for 12 weeks.

It is important that you keep taking the medicine until you finish the full course of treatment prescribed.

Even when you feel better, your doctor may decide to continue your treatment with Ranitidine Tablets in order to prevent the pain and discomfort returning.
Depending on the condition you are being treated for, the usual dosage may be 150mg or 300mg once daily or 150mg twice daily.

**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. This dose may be increased to 5 mg for each kg, twice a day. Take each dose about 12 hours apart.

**Older people**
Same dosage as for adults.

**Use in children and adolescents**

- **Children over 30 kg of weight and from 3 to 11 years:**
  Your doctor will work out the right dose based on your child’s weight.

- **Adolescents (12 years and over):**
  Same dosage as for adults.

If you take more Ranitidine Tablets than you should
Taking more than it says on the label is unlikely to be dangerous, unless many tablets are taken at once. In that case, phone your doctor or go to your nearest accident and emergency department straight away.

If you forget to take Ranitidine Tablets
Take another dose as soon as you remember. Then continue your dosage regimen (schedule) as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ranitidine Tablets
Please consult your doctor before you stop taking Ranitidine tablets. If you suddenly stop using this medicine, the symptoms that existed before your treatment may return.

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**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine. Stop taking Ranitidine tablets and see a doctor straight away, if you notice any of the following serious side effects, you may need urgent medical treatment:

- allergic reactions, the signs may include:
  - rash, itching or hives on the skin
  - swelling of your face, lips, tongue or other parts of the body
  - chest pain, shortness of breath, wheezing or having trouble breathing
  - unexplained fever and feeling faint, especially when standing up.
- kidney problems, which can lead to back pain, fever, pain when passing urine, blood in the urine and changes in blood tests.
- severe stomach pain, this may be a sign of something called ‘pancreatitis’.
- a slow or irregular heartbeat.

Check with your doctor as soon as possible if you notice any of the following:

**Uncommon side effects** (may affect up to 1 in 100 people)

- stomach-ache (abdominal pain)
- constipation
- feeling sick (nausea)

**Rare side effects** (may affect up to 1 in 1,000 people)

- skin rash

**Rare side effects that may show up in blood tests:**

- increase of serum creatinine in blood (kidney function test)
- changes to liver function

**Very rare side effects** (may affect up to 1 in 10,000 people)

- depression
- confusion, hallucinations (mainly reported in severely ill or elderly patients)
- blood disorders that may result in unusual tiredness, shortness of breath, more infections than usual, bruising more easily

- uncontrolled movements
- heart problems (slow or irregular heart rhythm)
- inflammation of the blood vessels which may cause reddening of areas of skin, localised pain and tenderness
- headaches (sometimes severe), dizziness
- diarrhoea
- blurred vision
- inflation of the pancreas (which may cause severe stomach pain)
- liver problems which may lead to jaundice (yellow colour of skin and the whites of eyes)
- red blotches or lumps on the skin, hair loss
- pain in the joints or muscles
- kidney problems that may cause changes in the amount and colour of water you pass
- if you are a man, sexual impotence that is normally reversible, tenderness of the breast, breast discharge and/or breast enlargement.

Many of these side effects are reversible and go away once ranitidine treatment is stopped.

**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 Website: www.mhra.gov.uk/yellowcard.

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

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**5. HOW TO STORE RANITIDINE TABLETS**

Keep this medicine out of the sight and reach of children. Do not use after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Store below 25°C in a dry place.

If it is out of date or you no longer want it, take it back to the pharmacy.

Do not use Ranitidine Tablets if you notice anything wrong with the medicine. Talk to your pharmacist.

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 to protect the environment.

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**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What Ranitidine Tablets contain:**
Each Ranitidine 150mg Tablet contains the active ingredient ranitidine hydrochloride, equivalent to ranitidine 150mg.
Each Ranitidine 300mg Tablet contains the active ingredient ranitidine hydrochloride, equivalent to ranitidine 300mg.
The other ingredients are Croscarmellose sodium, Magnesium stearate, Microcrystalline cellulose, Hydroxypropylmethylcellulose, Titanium dioxide, Talc, Polymethyle glycol 6000 and Polymethylmethacrylic acid copolymer.

**What Ranitidine Tablets look like and contents of the pack:**
Ranitidine 150mg Tablets are round, white to yellow film coated tablets. They are available in aluminium foil blister packs of 60 tablets.
Ranitidine 300mg Tablets are oblong, white to yellow film coated tablets. They are available in aluminium foil blister packs of 30 tablets.

**Marketing Authorisation Holder and Manufacturer:**
Mercury Pharmaceuticals Ltd., No.1 Croydon, 12-16 Addiscombe Road, Croydon CR0 0XT, UK.

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