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PACKAGE LEAFLET: INFORMATION FOR THE USER

Ranitidine 150 mg Film-coated Tablets
Ranitidine 300 mg Film-coated Tablets
Ranitidine 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 Film-coated Tablet is and what it is used for
2. What you need to know before you take Ranitidine Film-coated Tablets
3. How to take Ranitidine Film-coated Tablets
4. Possible side effects
5. How to store Ranitidine Film-coated Tablets
6. Contents of the pack and other information

1. WHAT RANITIDINE FILM-COATED TABLET IS AND WHAT IT IS USED FOR

Ranitidine Film-coated Tablet contains a medicine called ranitidine. This belongs to a group of medicines called H₂-receptor antagonists. It lowers the amount of acid in your stomach.

For adults (including the elderly) Ranitidine Film-coated Tablets is used to:

- heal and stop ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- help clear up infection in your stomach, when taken with antibiotic medicines (medicines taken to treat germs)
- stop 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 Film-coated Tablet is used to:

- heal ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- heal and stop 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 FILM-COATED TABLETS

Do not take Ranitidine Film-coated Tablets:

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

If you are not sure, talk to your doctor or pharmacist before taking Ranitidine Film-coated Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ranitidine Film-coated Tablets if:

- you have stomach cancer
- you have kidney problems. You will need to take a different amount of Ranitidine Film-coated Tablets
- you have had stomach ulcers before and you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines
- you have a rare condition called acute porphyria
- you are over 65 years old
- you have lung disease
- you are diabetic
- you have any problems with your immune system.

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

Other medicines and Ranitidine Film-coated Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Ranitidine Film-coated Tablets can affect the way some other medicines work. Also some other medicines can affect the way Ranitidine Film-coated Tablets works.

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
- lidocaine, a local anaesthetic
- propranolol, procainamide or n-acetylprocainamide, for heart problems
- diazepam, for worry or anxiety problems
- phenytoin, for epilepsy
- theophylline, for breathing problems (asthma)
- warfarin, for thinning your blood
- glipizide, for lowering blood glucose
- atazanavir or delaviridine, for treating HIV infection
- triazolam, for insomnia
- gefitinib, for lung cancer
- ketoconazole, an anti fungal medicine, sometimes used for treating thrush
- sucralfate, for treating stomach ulcers.

Midazolam is a medicine that may be given to you just before you have an operation. Tell the doctor you are taking Ranitidine Film-coated Tablets before your operation in case he or she wants to give you midazolam.

If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or nurse before taking Ranitidine Film-coated Tablets.

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. You should not take this medicine unless your doctor advises it is essential.

3. HOW TO TAKE RANITIDINE FILM-COATED 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.

Taking this medicine

- Take this medicine by mouth.
- Swallow each tablet whole with a glass of water.

The usual dose for an adult (including the elderly) is either:

- 150 mg in the morning and 150 mg in the evening, or
- 300 mg at bedtime.

Your exact dose will depend on your particular stomach condition, your doctor will tell you the dose you should take.

Use in children 12 years and over:
The adult dose is given.

Use in 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. This 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 Film-coated Tablets than you should

Ranitidine Film-coated is not normally harmful if you take more than you should, unless you take many tablets at once. If this applies to you (or someone else taking this medicine), you should go to your nearest hospital casualty department straight away.

