- Impotence
- Swollen, tender or leaking breasts
- Diarrhoea

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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: http://www.mhra.gov-.uk/yellowcard.

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

5. HOW TO STORE RANITIDINE 75 MG FILM-COATED TABLETS

Do not store above 25°C. Store in the original package

Keep out of the sight and reach of children.

Do not use after the expiry date stated on the carton and blister foil.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ranitidine 75mg film-coated tablets contain

The active substance is Ranitidine Hydrochloride 84 mg (equivalent to Ranitidine 75 mg).

The other ingredients are microcrystalline cellulose, magnesium stearate, hypromellose and titanium dioxide (E171).

What Ranitidine 75mg film-coated tablets look like and contents of the pack

Ranitidine 75mg film-coated tablets are white, round and film coated with a "K" logo on one side and 75 on the other.

Ranitidine 75mg film-coated tablets come in blisters of 6 and 12 tablets.

Marketing Authorisation Holder and Manufacturer

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Produced for: Numark Ltd.,

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PACKAGE LEAFLET: INFORMATION FOR THE USER

NUMARK O

Ranitidine 75mg film-coated tablets

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

Always take this medicine exactly as described in this leaflet or as your doctor 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.

What is in this leaflet:

- 1. What Ranitidine 75 mg film-coated tablets are and what they are used for
- What you need to know before you take Ranitidine 75 mg film-coated tablets
- 3. How to take Ranitidine 75 mg film-coated tablets
- 4. Possible side effects
- 5. How to store Ranitidine 75 mg film-coated tablets
- 6. Contents of the pack and other information

1. WHAT RANITIDINE 75 MG FILM-COATED TABLETS ARE AND WHAT THEY ARE USED FOR

Ranitidine 75 mg film-coated tablets are used to treat indigestion and heartburn for up to 12 hours in adults and children 16 years and over. The stomach produces acid which helps to digest food. Sometimes your stomach produces too much acid which can cause indigestion and heartburn.

The active ingredient is ranitidine hydrochloride which is a medicine called an H2 blocker. It works by preventing your stomach from producing too much acid.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RANITIDINE 75 MG FILM-COATED TABLETS

Do not take Ranitidine 75 mg film-coated tablets:

- If you are allergic (hypersensitive) to ranitidine or any of the other ingredients of Ranitidine tablets. See section 6 for ingredients.
- If you are under 16 years of age.

Warnings and precautions

Talk to your doctor before taking these tablets:

- If you have difficulty swallowing
- If you have liver or kidney problems
- If you have porphyria (too much of the pigment called porphyrin which may discolour the urine)
- If you have unintended weight loss
- If you are middle-aged or older with new or recently changed indigestion symptoms

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- If you have persistent stomach pain
- If you have had a peptic ulcer
- If you are under regular medical supervision
- If you are elderly
- If you have breathing problems
- If you have a weak immune system
- If you suffer from diabetes

Other medicines and Ranitidine 75mg film-coated tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription particularly medicines to prevent blood clotting, such as warfarin, medicines for insomnia (e.g. triazolam, midazolam), medicines for lowering blood glucose (e.g. glipizide), medicines for fungal infections (e.g. ketoconazole, itraconazole, posaconazole), medicines for treating HIV infection (e.g. atazanavir, delavirdine), medicines for lung cancer (e.g. gefitnib) and non-steroidal anti-inflammatory painkillers (e.g. aspirin or ibuprofen). This advice is even more important if you are elderly.

Taking Ranitidine 75mg film-coated tablets with food and drink

Ranitidine 75mg film-coated tablets may be taken before or after meals, as soon as you have symptoms.

Pregnancy and breast-feeding:

Talk to your doctor before taking Ranitidine 75mg film-coated tablets if you are pregnant, trying to become pregnant or are breast feeding.

Driving and using machines:

Ranitidine 75mg film-coated tablets have no known effects on the ability to drive or operate machinery. However, dizziness may occur as a side effect of this medicine.

3. HOW TO TAKE RANITIDINE 75 MG FILM-COATED TABLETS

Adults (including the elderly) and children 16 years of age and over: Swallow one tablet whole with a drink of water as soon as you have symptoms. If symptoms continue for more than one hour, take another tablet.

- Do not take more than 2 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.

If you take more Ranitidine 75mg film-coated tablets than you should Contact your doctor or casualty department

If you forget to take Ranitidine 75mg film-coated tablets

Do not take a double dose to make up for forgotten tablet. Take your next tablet at the normal time.

If you have any further questions on the use of this product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ranitidine 75mg film-coated tablets can cause side effects, although not everybody gets them.

Serious Allergic Reactions

If you experience any of these reactions, stop taking the medicine and seek medical help immediately:

- 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, dizziness especially when standing up

Other Serious Side Effects

- Kidney problems, which can lead to back pain, fever, pain when passing urine, blood in the urine and changes in blood tests.
- Hepatitis (swollen liver). This can lead to feeling sick or being sick, loss of appetite or generally feeling unwell, itching, fever, yellowing of the skin and eyes or dark coloured urine.
- Pancreatitis, which can lead to severe abdominal pain, nausea and fever.
- Slow or irregular heartbeat.
- Blood count changes, which could cause you to have an increased risk of infection, or have a tendency to bruise or bleed more easily.
- Skin reaction (erythema multiforme)

If you experience any of the above side effects tell your doctor IMMEDIATELY or go to a casualty department at your nearest hospital.

Other Possible side effects:

Uncommon side effects (experienced by between 1 in 100 and 1 in 1000 patients)

• Abdominal pain, constipation, nausea

Rare side effects (experienced by between 1 in 1000 and 1 in 10000 patients)

- · Liver enzyme increases which may have an effect on some medical tests
- · Rise in plasma creatinine which may show up in kidney function tests
- Skin rash

Very rare side effects (experienced by less than 1 in 10,000 patients)

- Feeling confused, seeing or hearing unexplained things (hallucinations)
- Depression
- Headache, dizziness or blurred vision
- Inflammation of your blood vessels (known as 'vasculitis). Sign of this
 can include a rash, swollen joints or kidney problems
- Unexplained hair loss
- · Aches and painful in your muscles and joints
- Difficulty controlling muscles