# RANITIDINE 75MG TABLETS

(Ranitidine)

PL 20395/0079

UK PAR

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RANITIDINE 75MG TABLETS

PL 20395/0079

LAY SUMMARY

The MHRA granted Relonchem Limited a Marketing Authorisation (licence) for the medicinal product Ranitidine 75mg Tablets on 28 July 2011. This medicine is available on the General Sales List (GSL) and can be purchased at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

Ranitidine 75mg Tablets are used to relieve the burning sensation in the stomach and chest caused by heartburn, indigestion, acid indigestion and hyperacidity (too much acid).

This medicine contains the active ingredient ranitidine which belongs to a group of medicines called H2-antagonists. It works by preventing your stomach from producing too much acid and its effects last for up to twelve hours.

This application is a duplicate of a previously granted application for Ranitidine 75mg Tablets/Ranzac 75mg Tablets (PL 19348/0110), which was granted to the Marketing Authorisation Holder LPC Medical Ltd on 02 February 2005.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Ranitidine 75mg Tablets outweigh the risks; hence a Marketing Authorisation has been granted.
RANITIDINE 75 MG TABLETS

PL 20395/0079

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted a Marketing Authorisation for the medicinal product Ranitidine 75mg Tablets (PL 20395/0079) to Relonchem Limited on 28 July 2011. This medicine is available on the General Sales List (GSL) and can be purchased at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist and indicated for the short term symptomatic relief of heartburn, indigestion, acid indigestion and hyperacidity.

This product contains the active ingredient ranitidine, which is a competitive inhibitor of the action of histamine at the histamine H2-receptors. It inhibits basal gastric acid secretion as well as gastric acid secretion stimulated by e.g. histamine, pentagastrin or food. Ranitidine reduces gastric acid secretion as well as to a limited degree total pepsin output and total gastric juice volume.

The application was submitted as a simple abridged application according to Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC, cross-referring to Ranitidine 75mg Tablets/Ranzac 75mg Tablets (PL 19348/0110) approved on 02 February 2005 to the Marketing Authorisation Holder LPC Medical Ltd.

No new data were submitted nor were they necessary for this simple application, as the data are identical to that of the previously granted cross-reference product.
1 INTRODUCTION
This is a simple, informed consent application for Ranitidine 75mg Tablets submitted under Article 10(c) of Directive 2001/83/EC. The application cross-refers to Ranitidine 75mg Tablets/Ranzac 75mg Tablets (PL 19348/0110) approved on 02 February 2005 to the Marketing Authorisation Holder LPC Medical Ltd.

The current application is considered valid.

2 MARKETING AUTHORISATION APPLICATION (MAA)

2.1 Name(s)
The proposed name of the product is Ranitidine 75mg Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
The product contains ranitidine 75mg and is packaged in blister strips comprised of aluminium foil on both sides in pack sizes of 5, 6, 10 or 12 tablets.

The proposed shelf life is 36 months with the storage conditions ‘Store in the original package. Do not store above 25ºC’

The proposed shelf-life and storage conditions are consistent with the details registered for the cross-referenced product.

2.3 Legal status
On approval, the product will be available on the General Sales List (GSL).

2.4 Marketing Authorisation Holder/Contact Persons/Company
The proposed Marketing Authorisation Holder is Relonchem Limited, 27, Old Gloucester Street, London, WC1, 3XX.

The Qualified Person (QP) responsible for pharmacovigilance is stated and their CV is included.

2.5 Manufacturers
The proposed manufacturing site is consistent with that registered for the reference product and evidence of compliance with current Good Manufacturing Practice has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the reference product and the maximum batch size is stated.
2.8 Finished product/shelf-life specification
The proposed finished product specifications are in line with the details registered for the reference product.

2.9 Drug substance specification
The proposed drug substance specifications are consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
No materials of human or animal origin have been used in the manufacture of these products. This is consistent with the reference product.

2.11 Bioequivalence
No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula utilising the same process as the reference product Ranitidine 75mg Tablets/Ranzac 75mg Tablets (PL 19348/0110).

3  EXPERT REPORT
The applicant has included a detailed pharmaceutical expert report, written by an appropriately qualified person.

4.  PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to that of the reference product.

5.  SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The proposed SmPC is consistent with the details registered for the reference product.

6.  PATIENT INFORMATION LEAFLET (PIL)/LABELLING
PIL
The patient information leaflet has been prepared in line with the details registered for the reference product.

The applicant has previously submitted results of PIL user testing for the reference product Ranitidine 75mg Tablets/Ranzac 75mg Tablets (PL 19348/0110). The results indicate that the PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains. As the leaflet for Ranitidine 75mg Tablets/Ranzac 75mg Tablets (PL 19348/0110) and this product is considered the same, no further user testing of the leaflet for this product is necessary.

Carton and blister
The proposed artwork complies with the relevant statutory requirements. In line with current legislation, the applicant has also included the name of the product in Braille on the outer packaging.

7.  CONCLUSIONS
The data submitted with this application is acceptable. The grant of a Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

As this application is identical to the reference product Ranitidine 75mg Tablets/Ranzac 75mg Tablets (PL 19348/0110), no new non-clinical data have been supplied with this application and none are required. A non-clinical expert report has been written by a suitably qualified person and is satisfactory.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA). As the application is for an identical version of an already authorised reference product, it is not expected that the environmental exposure to ranitidine will increase following the marketing approval of the proposed product.
CLINICAL ASSESSMENT

As this application is identical to the reference product Ranitidine 75mg Tablets/Ranzac 75mg Tablets (PL 19348/0110), no new clinical data have been supplied with this application and none are required. A clinical expert report has been written by a suitably qualified person and is satisfactory.

The Marketing Authorisation Holder has provided a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that the Marketing Authorisation Holder has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
The data for this application is consistent with that previously assessed for the reference product and as such have been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type.

EFFICACY
This application is identical to the previously granted application for Ranitidine 75mg Tablets/Ranzac 75mg Tablets (PL 19348/0110), granted to LPC Medical Ltd on 02 February 2005.

SAFETY
No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE
The SmPC, PIL and labelling are satisfactory and consistent with that for the reference product.

Colour mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements.

BENEFIT/RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the reference product. Extensive clinical experience with ranitidine is considered to have demonstrated the therapeutic values of the compound. The benefit/risk is therefore considered to be positive.
## STEPS TAKEN FOR ASSESSMENT

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<td>1</td>
<td>The MHRA received the Marketing Authorisation Application on 04 June 2010.</td>
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<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 22 June 2010.</td>
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<td>Following assessment of the application the MHRA requested further information on 20 August 2010, 02 March 2011 and 06 June 2011.</td>
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<td>The applicant responded to the MHRA’s request, providing further information on 15 February 2011, 19 April 2011 and 20 June 2011.</td>
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<td>5</td>
<td>The application was determined on 28 July 2011.</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Ranitidine 75mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
75mg Ranitidine (as hydrochloride)

3 PHARMACEUTICAL FORM
Coated tablet White to off-white, round biconvex film coated tablets with a break line on one side and the imprint "R75" on the other side.

4 CLINICAL PARTICULARS
4.1 THERAPEUTIC INDICATIONS
Ranitidine 75mg Tablets are indicated for the short term symptomatic relief of heartburn, indigestion, acid indigestion and hyperacidity.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
Adults: One Ranitidine 75mg Tablet should be taken as soon as symptoms appear. If symptoms persist for more than one hour, or return a second Ranitidine 75mg Tablet should be taken. The maximum daily dose is two Ranitidine 75mg Tablets.

Children: Ranitidine 75mg Tablets should not be taken by children under the age of 16 years.

Length of Treatment: Do not take the tablets for more than 6 days without the advice of a pharmacist or doctor. Medical attention should be sought if symptoms worsen.
Method of administration: Ranitidine 75mg tablets should be swallowed whole with fluid.

4.3 CONTRAINDICATIONS
Ranitidine 75mg Tablets should not be given to patients known to have hypersensitivity to Ranitidine or any component of the tablet.

Ranitidine 75mg Tablets should not be given to children under 16 years because safety and efficacy have not been established in this patient group.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Patients should be advised not to purchase a second pack of tablets without the advice of a pharmacist or doctor.

Patients taking NSAIDS, especially the elderly, should seek their doctor's advice before using this product.

If gastric ulcer has been diagnosed or there is a new or recently changed presentation or dyspeptic symptoms, then the possibility of malignancy should be excluded. Isolated reports suggest a relationship between the intake of Ranitidine 5mg and the occurrence of acute porphyria. Administration of Ranitidine 75mg Tablets to patients with a history of acute porphyria should, therefore be avoided.

Patients should consult their doctor before taking Ranitidine 75mg Tablets if the patient has:
- Unintended weight loss.
- Patient has problems swallowing.
- Constant stomach pains.

And if the patient is middle-aged or elderly with new or recently changed symptoms.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
At normal dosage, Ranitidine does not inhibit cytochrome P450; although some minor interactions have been seen with some products these have not been shown to be of clinical relevance.

4.6 PREGNANCY AND LACTATION
Pregnancy: There are no adequate studies on the effect of Ranitidine in pregnancy although animal studies have not produced evidence that it will harm the foetus. Like other medicines, Ranitidine should only be used during pregnancy if absolutely necessary following appropriate medical consultation.
Lactation: Ranitidine is found in human breast milk so nursing mothers should avoid taking ranitidine.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
No effects have been reported.

4.8 UNDESIRABLE EFFECTS
Ranitidine is well tolerated although as with all drugs, some patients occasionally experience side effects. Listed below are side effects which have been reported for Ranitidine 75mg Tablets. These have not necessarily occurred after taking Ranitidine 75mg Tablets and could have occurred after taking 150mg and 300mg Ranitidine.

Frequency estimate: Very common: >1/10; common >1/100, <1/10; uncommon >1/1,000, <1/100; rare >1/10,000, <1/1,000; very rare <1/10,000 and isolated reports.

**Hypersensitivity reactions:**
- Rare: Hypersensitivity reactions, including urticaria, fever, hypotension, angioneurotic oedema, bronchospasm
- Very rare: Anaphylactic shock, vasculitis or vasculitic rash.

**Isolated cases:** Acute interstitial nephritis

**Blood and lymphatic system disorders:**
- Very rare: Leucopenia, thrombocytopenia, agranulocytosis or pancytopenia, sometimes with marrow hypoplasia or aplastic anaemia. These effects were usually reversible.

**Cardiac disorders:**
- Very rare: Arrhythmia, such as tachycardia or bradycardia, A-V conduction disturbance.

**Gastrointestinal:**
- Very rare: Nausea, diarrhoea, acute pancreatitis

**Hepatobiliary disorders:**
- Rare: Transient and reversible changes in liver function test values
- Very rare: hepatitis and jaundice, usually reversible

**Musculoskeletal disorders:**
- Very rare: Arthralgia, myalgia

**Nervous system/psychiatric disorders:**
- Rare: Headache, dizziness
- Very rare: Severe headache, confusion, hallucinations, involuntary movement disorders and depression. These have been reported, mainly in elderly or severely ill patients

**Skin and subcutaneous tissue disorders** (see also hypersensitivity)
- Rare: Skin rash
- Very rare: Erythema multiforme, alopecia

**Other:**
- Very rare: Gynaecomastia, erectile dysfunction, visual disturbances

4.9 OVERDOSE
Complications from overdose are not expected after oral administration. Daily doses of 6300mg of ranitidine administered orally for several months were well tolerated.

Treatment for overdose: If there are signs of intoxication, unabsorbed tablets should be removed by gastric lavage. Haemodialysis can be used to remove drug from the plasma.

Symptomatic and supportive treatment should be given as required.

5 PHARMACOLOGICAL PROPERTIES
5.1 PHARMACODYNAMIC PROPERTIES
Ranitidine is a competitive inhibitor of the action of histamine at the histamine H2-receptors. It inhibits basal gastric acid secretion as well as gastric acid secretion stimulated by e.g. histamine, pentagastrin or food.
Ranitidine reduces gastric acid secretion as well as to a limited degree total pepsin output and total gastric juice volume.

Studies showed that therapeutic doses of 150 mg ranitidine twice a day, on average, inhibit gastric acid secretion by more than 60% for 24 hours. At night these doses were sufficient to inhibit gastric acid secretion by 70-90%. Doses of 150 mg in the evening were shown to inhibit gastric acid secretion by 40-70% for 24 hours on average.

Therapeutic doses necessary to inhibit gastric acid secretion by 50-60% for 24 hours were 300 mg ranitidine. Nocturnal gastric acid secretion was reduced by almost 90%.

5.2 PHARMACOKINETIC PROPERTIES
Ranitidine is rapidly absorbed after oral administration with mean peak levels occurring at 1.25 to 3 hours. Bioavailability of ranitidine tablets is 50% on average with an interindividual variability of 28-76%.

After oral administration of 150 mg ranitidine mean peak plasma levels were about 400 ng/ml. Interindividual variability was observed. After 12 hours, mean plasma levels were 40 ng/ml. After oral administration of 300 mg ranitidine mean peak plasma levels were 700 to 800 ng/ml.

In several studies, the plasma concentration necessary to inhibit 50% of gastric acid secretion in adults was between 73 and 165 ng/ml. Plasma-protein binding is approximately 15%. The volume of distribution is 1.2-1.8 l/kg in adults and 2.5 l/kg in children. Mean total clearance is 570-710 ml/min in adults and about 800 ml/min in children and young persons.

5.3 PRECLINICAL SAFETY DATA
Ranitidine has a high safety margin. In dogs, oral doses of ranitidine of up to 400 mg/kg/day for 54 weeks resulted in dose related occasional cases of mild diarrhoea, increased salivation and vomiting. Rapid respiration and muscular tremors with one fatality occurred in dogs receiving 450 mg/kg ranitidine. Rats tolerated daily doses of 2,000 mg/kg for 78 weeks well.

In animal tests ranitidine has shown no mutagenic, carcinogenic or teratogenic potential and does not impair fertility.

6 PHARMACEUTICAL PARTICULARS
6.1 LIST OF EXCIPIENTS
Microcrystalline Cellulose, Polyvidone, Magnesium Stearate, Methylhydroxypropylcellulose, Titanium dioxide (E171), Talc, Macrogol6000 and Methacrylic acid copolymer.

6.2 INCOMPATIBILITIES
None known.

6.3 SHELF LIFE
36 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE
Store in the original package. Do not store above 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER
Blister strip comprising aluminium foil on both sides. The strips are packed in cartons to contain 5, 6, 10 or 12 tablets.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL
None

7 MARKETING AUTHORISATION HOLDER
Relonchem Limited
27, Old Gloucester Street
London
WC1 3XX
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<th>MARKETING AUTHORISATION NUMBER(S)</th>
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**PRODUCT INFORMATION LEAFLET**

Ranitidine 75mg TABLETS
(Ranitidine 75mg tablets)

**Patient Information Leaflet**

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Ranitidine 75mg Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**
1. What Ranitidine 75mg Tablets are and what they are used for
2. Before you take Ranitidine 75mg Tablets
3. How to take Ranitidine 75mg Tablets
4. Possible side effects
5. How to store Ranitidine 75mg Tablets
6. Further information

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

The name of your medicine is Ranitidine 75mg Tablets. It contains the active ingredient called Ranitidine Hydrochloride.

Ranitidine belongs to a group of medicines called H2-antagonists. It works by preventing your stomach from producing too much acid and its effects last for up to 12 hours.

The tablets are used to relieve the burning sensation in the stomach and chest caused by heartburn, indigestion, acid indigestion and hyperacidity (too much acid).

2. BEFORE YOU TAKE RANITIDINE 75MG TABLETS

Do not take Ranitidine 75mg Tablets if you have an allergy to Ranitidine or to any of the ingredients listed at the end of this leaflet.

If you are not sure whether you should start taking Ranitidine 75mg Tablets, talk to your doctor.

Ranitidine 75mg Tablets is not recommended for children under 16 years old.

You must tell your doctor or pharmacist if you:
- have been told by a doctor that you have an ulcer in the stomach or small intestine (lower part of your stomach)
- have kidney and/or liver problems
- are under regular medical supervision for other reasons
- are suffering from any other illness or taking medications either prescribed by a physician or prescribed by yourself
- have lost weight unintentionally linked with symptoms of indigestion
- are middle-aged or elderly with new or recently changed symptoms of indigestion
- are taking non-steroidal anti-inflammatory painkillers (NSAIDs, such as Aspirin)
- have the rare condition called porphyria
- are pregnant, or intend to become pregnant
- are breast-feeding or intend to breast-feed

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO TAKE RANITIDINE 75MG TABLETS

Swallow one tablet (75mg of Ranitidine) whole with water as soon as symptoms appear.

If symptoms are not controlled or return within one hour, swallow another tablet.

For prevention of heartburn associated with consuming food and drink, indigestion, acid indigestion and hyperacidity (too much acid), swallow one tablet with water, half to one hour beforehand.

Do not take more than two tablets (150mg of Ranitidine) in 24 hours.

Medical attention should be sought if symptoms worsen.

Do not take tablets for more than 6 days without the advice of a pharmacist or doctor.
If you take more Ranitidine 75mg Tablets than you should:
Immediate medical advice should be sought in the event of taking too many tablets or an overdose, even if you feel well.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ranitidine 75mg Tablets can cause side effects, although not everybody gets them.
You must stop taking the tablets and tell your doctor immediately, if your chest suddenly feels tight and you start to wheeze or get a skin rash or swelling of the face, lips, throat and eyelids.
Check with your doctor as soon as possible if any of these side effects are noticed:

Rare
- Headache
- Dizziness
- Changes to blood counts (causing tiredness, bruising, fever or frequent infections)
- Diarrhoea
- Nausea
- Muscle and joint pains
- Jaundice or yellowing of the skin
- Abnormally low blood pressure
- Acute pancreatitis (inflammation of the pancreas, which causes severe pain in the abdomen and back)
- Highly or excessively sensitive reactions like an itchy skin eruption
- Rare cases of hepatitis, with or without jaundice (which are usually reversible)

Very rare
- Visual disturbances
- Changes in heart rate (faster or slower)
- Vasculitis (inflammation of blood vessels) or a rash related to vasculitis, inflammation of the kidney which can cause swollen ankles or high blood pressure
- Breast enlarge
- Erectile dysfunction (impotence) in men
- Severe headache, confusion, hallucinations or depression (mainly in elderly or severely ill patients)

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

5. HOW TO STORE RANITIDINE 75mg TABLETS

Keep out of the reach and sight of children.
Store in the original pack. Do not store above 25°C.
Do not take Ranitidine 75mg Tablets after the expiry date (EXP) printed on the pack. The expiry date refers to the last day of that month.
If you have any Ranitidine 75mg Tablets left, return them to your pharmacist.
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

What is in Ranitidine 75mg Tablets?
Each tablet contains 75mg Ranitidine as Ranitidine Hydrochloride.
The tablet also contains Microcrystalline Cellulose, Povidone, Magnesium Stearate, Hypromellose, Talc, Macrogol 6000, Methacrylic acid copolymer and the colouring agent E171.
Ranitidine 75mg Tablets are white to off-white, round biconvex film coated tablets with a break line on one side and the imprint “R75” on the other side.
Pack sizes: 5, 6, 10, 12. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Relonchem Ltd.,
27 Old Gloucester Street, London WC1 3XX
Telephone: 02074195043
Fax: 02074195024
Email: info@relonchem.com

PL 20395/0079

This leaflet was last revised in March 2008
Blister:

MHRA PAR-Ranitidine 75mg Tablets