RANITIDINE 75 MG FILM-COATED TABLETS
PL 21880/0133

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RANITIDINE 75 MG FILM-COATED TABLETS
PL 21880/0133

LAY SUMMARY

On 22nd June 2012, the MHRA granted Medreich PLC a Marketing Authorisation (licence) for Ranitidine 75 mg Film-Coated Tablets.

Ranitidine 75 mg Film-Coated Tablets contains the active ingredient, ranitidine hydrochloride.

Ranitidine hydrochloride belongs to a group of medicines called histamine H2 antagonist. It works by reducing the natural production of acid in the stomach.

Ranitidine 75 mg Film-Coated Tablets are used for the symptomatic relief of heartburn, indigestion and too much acid in the stomach.

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

RANITIDINE 75 MG FILM-COATED TABLETS
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SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Marketing Authorisation for the medicinal product Ranitidine 75 mg Film-Coated Tablets (PL 21880/0133) to Medreich PLC on 22nd June 2012. This medicine has a General Sales Licence (GSL) and is indicated for the symptomatic relief of heartburn, indigestion, acid indigestion and hyperacidity.

This application for Ranitidine 75 mg Film-Coated Tablets is submitted according to Article 10c of Directive 2001/83/EC, cross-referring to Ranitidine 75 mg Film-Coated Tablets, originally authorised to Karib Kemi-Pharm Limited on 22nd July 2005 (PL 18224/0028). This licence underwent a change of ownership to Medreich PLC on 16th September 2008 (PL 21880/0022).

It is considered that the pharmacovigilance system as described by the applicant fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance together with the necessary means for notification of any adverse reaction suspected of occurring.

A satisfactory justification has been provided for the absence of a Risk Management Plan.

No new data were submitted nor were they necessary for this “informed consent” application, as the data are identical to that of the previously granted cross-reference product.

PHARMACEUTICAL ASSESSMENT

LICENCE NO:	PL 21880/0133
PROPRIETARY NAME:	Ranitidine 75 mg Film-Coated Tablets
ACTIVE(S):	Ranitidine hydrochloride
COMPANY NAME:	Medreich PLC
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC
LEGAL STATUS:	GSL

1. INTRODUCTION

This is an "informed consent" application for Ranitidine 75 mg Film-Coated Tablets (PL 21880/0133) submitted under Article 10c of Directive 2001/83/EC. The proposed Marketing Authorisation Holder (MAH) is Medreich PLC, 9 Royal Parade, Kew Gardens, Surrey, TW9 3QD.

This application cross-refers to Ranitidine 75 mg Film-Coated Tablets, originally authorised to Karib Kemi-Pharm Limited on 22nd July 2005 (PL 18224/0028). This licence underwent a change of ownership to Medreich PLC on 16th September 2008 (PL 21880/0022).

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 NAME(S)

The proposed name of the product is Ranitidine 75 mg Film-Coated 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 75 mg of ranitidine hydrochloride as the active ingredient in a tablet administered orally. The finished product is packaged in blister strips comprised of:
- Aluminium foil soft, mat side primered and lacquer laminated against Polyamide 0,025 mm (Nylon 6), bright side lacquer laminated against polyvinyl chloride (PVC) 0,060 mm.

- Aluminium-foil hard, mat side lacquered with clear heat resistant print primer, bright side heat seal lacquered to seal to PVC and polyvinylidene chloride (PvDC).

The blister strips are packed into a pre-printed carton. Pack sizes are 6 and 12 tablets.

The proposed shelf-life is 36 months with storage conditions 'Do not store above 25°C.' This is consistent with the details registered for the cross-reference product.

2.3 Legal status

General Sales Licence (GSL).

2.4 Marketing authorisation holder/Contact Persons/Company

Medreich PLC, 9 Royal Parade, Kew Gardens, Surrey, TW9 3QD.
The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers

The manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

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

2.7 Manufacturing process
The manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The finished product specification is in-line with the details registered for the cross-reference product.

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

2.10 TSE Compliance
The excipients used are identical to those in the cross-reference products and declarations have been provided to confirm that none contain material of human origin. A declaration has been provided that confirms that the magnesium stearate contained in this product is sourced from vegetable origin.

3. OVERALL SUMMARIES
The applicant has included the quality, non-clinical and clinical overall summaries in Module 2 of the applications. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

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

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

6. PATIENT INFORMATION LEAFLET (PIL)/LABELLING
PIL

The PIL text is consistent with the PIL text for the cross-reference product. A bridging statement has been submitted along with the user testing for an already approved product.

The results of consultations with target patient groups ("user testing") are in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet 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 they contain. This is satisfactory.

Labelling
The labelling text is consistent with the labelling text for the cross-reference product and complies with statutory requirements.

7. CONCLUSIONS

The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.

NON-CLINICAL ASSESSMENT

No new non-clinical data have been supplied with this application and none are required for an application of this type.

A satisfactory justification has been provided for the absence of an Environmental Risk Assessment.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with those previously approved for the cross-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 consistent with the details of the previously granted application, Ranitidine 75 mg Film-Coated Tablets, originally authorised to Karib Kemi-Pharm Limited on 22nd July 2005 (PL 18224/0028). This licence underwent a change of ownership to Medreich PLC on 16th September 2008 (PL 21880/0022).

No new or unexpected safety concerns arise from this application.

At the time of assessment, the SmPC, PIL and labelling are satisfactory and consistent with those of the cross-reference product.

RISK BENEFIT 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 cross-reference product. Extensive clinical experience with ranitidine hydrochloride is considered to have demonstrated the therapeutic value of the compound. The risk:benefit balance is therefore considered to be positive.

RANITIDINE 75 MG FILM-COATED TABLETS
PL 21880/0133

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the Marketing Authorisation Application on 18th May 2011.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 8th June 2011.
3	Following assessment of the application further information was requested regarding the quality section of the dossier on 10th June 2011.
4	The applicant responded to the MHRA's requests, providing further information on 8th August 2012 for the quality section.
5	The application was determined on 19th June 2012. The application was completed on 22nd June 2012.

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ranitidine 75 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains ranitidine 75 mg (as the hydrochloride).
For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.
White coloured, round, biconvex film coated tablets with k logo on one face and 75 on the other.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Symptomatic relief of heartburn, indigestion, acid indigestion and hyperacidity.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Route of Administration
Oral

Dosage
Adults (Including the Elderly) and children 16 years of age and older:
Swallow one Ranitidine 75 mg film-coated tablet whole, with a drink of water, as soon as you have symptoms. If symptoms persist for more than one hour or return, take another tablet.

Do not take more than two tablets in 24 hours.
Do not take the tablets for more than 6 days without the advice of a pharmacist or doctor.

Children under 16 years
Not recommended for children under 16 years of age

4.3 CONTRAINDICATIONS

Ranitidine is contra-indicated for people known to be hypersensitive to the drug or any ingredients of Ranitidine 75mg Film-coated tablets.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Treatment with a histamine H2-antagonist such as ranitidine may mask symptoms associated with carcinoma of the stomach and may therefore delay diagnosis of the condition.

Ranitidine is excreted via the kidney and so plasma levels of the drug are increased in patients with severe renal impairment. Ranitidine 75 mg film-coated tablet is not suitable for these patients.

People taking non-steroidal anti-inflammatory drugs, especially those with a history of peptic ulcer andthe elderly should not self-medicate with Ranitidine 75 mg film-coated tablet but seek their doctor's advice before use.

People with a history of porphyria should avoid use of the product.

Consumers will be advised not to purchase a second pack of tablets without the advice of a pharmacist of doctor.

The product is not indicated in the following people without seeking their doctor's advice:

- Patients with severe renal and/or hepatic impairment.
- Patients under regular medical supervision for other reasons.
- Patients taking medications either physician prescribed or self prescribed.
- Those with difficulty swallowing, persistent stomach pain or unintended weight loss in association with symptoms of indigestion.
- Those who are middle-aged or elderly with new or recently changed symptoms of indigestion.

In patients such as the elderly, persons with chronic lung disease, diabetes or the immunocompromised, there may be an increased risk of developing community acquired pneumonia.

A large epidemiological study showed an increased risk of developing community acquired pneumonia in current users of H2 receptor antagonists versus those who had stopped treatment, with an observed adjusted relative risk increase of 1.82 (95% CI, 1.26–2.64).

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Ranitidine has the potential to affect the absorption, metabolism or renal excretion of other drugs. The altered pharmacokinetics may necessitate dosage adjustment of the affected drug or discontinuation of treatment.

Interactions occur by several mechanisms including:

1) Inhibition of cytochrome P450-linked mixed function oxygenase system:
Ranitidine at usual therapeutics doses does not potentiate the actions of drugs which are inactivated by this enzyme systems such as diazepam, lidocaine, phenytoin, propranol and theophylline.
There have been reports of altered prothrombin time with coumarin anticoagulants (e.g. warfarin). Due to the narrow therapeutic index, close monitoring of increased or decreased prothrombin time is recommended during concurrent treatment with ranitidine.

2) Alteration of gastric pH:
The bioavailability of certain drugs may be affected. This can result in either an increase in absorption or a decrease in absorption.

4.6 PREGNANCY AND LACTATION

Ranitidine crosses the placenta but therapeutic doses administered to obstetric patients in labour or undergoing caesarean section have been without any adverse effect on labour, delivery or subsequent neonatal progress.

Like other over the counter drugs it should not be taken during pregnancy without consulting a doctor or pharmacist. It is also excreted in human breast milk and women who are breast-feeding will be advised to speak to their doctor before taking Ranitidine tablets.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No known effect

4.8 UNDESIRABLE EFFECTS

The following convention has been utilised for the classification of undesirable effects: very common (>1/10), common (>1/100, <1/10), uncommon (>1/1000, <1/100), rare (>1/10,000, <1/1000), very rare (1/10,000).

Adverse event frequencies have been estimated from spontaneous reports from post-marketing data.

Hepatobiliary Disorders:
Rare: Transient and reversible changes in liver function tests.
Very Rare: Hepatitis (hepatocellular, hepatocanalicular or mixed) with or without jaundice. These were usually reversible.

Gastrointestinal Disorders:
Very Rare: Acute pancreatitis and diarrhoea.
Uncommon: Abdominal pain, constipation, nausea. (these symtoms mostly improved during continued treatment).

Blood & Lymphatic System Disorders
Very rare: Blood count changes (Leucopenia and thrombocytopenia). These are usually reversible. Agranulocytosis or pancytopenia, sometimes with marrow hypoplasia or aplasia.

Immune System Disorders:
Rare: Hypersensitivity reactions (urticaria, angioneurotic oedema, fever, bronchospasm, hypotension, chest pain)

Very rare: Anaphylactic shock.
These reactions have occasionally occurred after a single dose.

Cardiac Disorders:
Very Rare: As with other H2 receptor antagonists bradycardia and A-V block.

Nervous System Disorders:
Very rare: Headache (sometimes severe), dizziness and reversible involuntary movement disorders .

Psychiatric Disorders:
Very rare: reversible mental confusion, depression and hallucinations
These have been reported, predominantly in severely ill and elderly patients.

Skin and Subcutaneous Tissue Disorders:
Rare: Skin rash
Very rare: erythema multiforme and alopecia.

Musculoskeletal and Connective Tissue Disorders:
Very rare: Musculoskeletal symptoms such as arthralgia and myalgia

Eye Disorders:
Very Rare: Reversible blurred vision.
There have been reports of blurred vision, which is suggestive of a change of accommodation.

Vascular Disorders:
Very Rare: Vasculitis

Renal and Urinary Disorders:
Very Rare: Acute interstitial nephritis
Rare: Elevation of plasma creatinine (usually slight; normalised during continued treatment)

Reproductive System and Breast Disorders:
Very Rare: Reversible impotence. Breast symptoms and conditions (such as gynaecomastia and galactorrhea)

Discontinuation of therapy may be necessary in order to establish the underlying cause.
No clinically significant interference with endocrine or gonadal function has been reported.

4.9 OVERDOSE

Ranitidine is very specific in action and accordingly no particular problems are expected following overdosage. Symptomatic and supportive therapy should be given as appropriate. If need be, the drug may be removed from the plasma by haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Ranitidine is a specific rapidly acting histamine H2-antagonist. It inhibits basal and stimulated secretion of gastric acid, reducing both the volume and the acid and pepsin content of the secretion.

Ranitidine has a long duration of action and so a single 75mg dose effectively suppresses gastric acid secretion for twelve hours.

Clinical studies have shown that Zantac 75 mg can relieve the symptoms of excess acid production for up to twelve hours.

5.2 PHARMACOKINETIC PROPERTIES

The bioavailability of ranitidine is consistently about 50%. Absorption of ranitidine after oral administration is rapid and peak plasma concentrations are usually achieved within 2-3 hours of administration. Absorption is not significantly impaired by food or antacids. Ranitidine is not extensively metabolised. Elimination of the drug is primarily by tubular secretion. The elimination half-life of ranitidine is approximately 2-3 hours. In balance studies with 150mg 3H-ranitidine 60-70% of an oral dose was excreted in urine and 26% in faeces. Analysis of urine excreted in the first 24 hours after dosing showed that 35% of the oral dose was eliminated unchanged. About 6% of the dose is

excreted as the N-Oxide, 2% as the S-Oxide, 2% as desmethyl ranitidine and 1-2% as the furoic acid analogue.

5.3 PRECLINICAL SAFETY DATA

Extensive studies have been carried out in animals. The pharmacology of ranitidine hydrochloride shows it to be a surmountable H2 receptor antagonist which produces an inhibition of gastro acid secretion. Extensive toxicological investigators have been conducted which predicted a very safe profile for clinical use. This safety has been confirmed by extensive use in patients for many years.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Microcrystalline cellulose
Magnesium stearate
Hypromellose
Titanium dioxide.

6.2 INCOMPATIBILITIES

Not applicable.

6.3 SHELF LIFE

36 months.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

6 and 12 tablets; Tablets packed individually in a foil/blister strip;
Blister strips are inserted into pre-printed carton.

- Aluminium foil soft, mat side primered and lacquer laminated against Polyamide 0,025 mm (Nylon 6), bright side lacquer laminated against PCV 0,060 mm.

- Aluminium-foil hard, mat side lacquered with clear heat resistant print primer, bright side heat seal lacquered to seal to PVC and PvDC.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Not applicable.

7 MARKETING AUTHORISATION HOLDER

MEDREICH PLC
9 ROYAL PARADE,
KEW GARDENS
SURREY,
TW9 3QD

8 MARKETING AUTHORISATION NUMBER(S)

PL 21880/0133

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22/06/2012

10 DATE OF REVISION OF THE TEXT

22/06/2012

PATIENT INFORMATION LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

RANITIDINE

75 mg film-coated tablets

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 them.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after two weeks.
- 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
- Never offer your medicine to other people. It may not be suitable for them even if their symptoms are the same as yours

In this leaflet:

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

Your medicine is known as a histamine H2 antagonist. It works by reducing the natural production of acid in the stomach.

Ranitidine film-coated tablets are used for the symptomatic relief of heartburn, indigestion, acid indigestion and too much acid in the stomach.

It is not intended for patients with any of the following conditions without seeking the advice of your doctor or pharmacist:
- Patients with severe kidney or liver impairment
- Patient under regular medical supervision for other reasons
- Patients taking medications either physician prescribed or self-prescribed
- Patients with difficulty swallowing, persistent stomach pain or unintended weight loss in association with symptoms of indigestion
- Patients of middle age or older with new or recently changed symptoms of indigestion

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2. BEFORE YOU TAKE RANITIDINE FILM-COATED TABLETS

Do not take Ranitidine film-coated tablets:
- if you are hypersensitive (allergic) to ranitidine or any of the other ingredients of Ranitidine film-coated tablets.

Take special care and tell your doctor before taking this medicine if you:
- have a kidney problem
- have had a stomach ulcer or a duodenal ulcer in the past
- have a rare illness called porphyria
- have breathing or heart problems
- have weak immune system

This section is continued overleaf →

- suffer from diabetes
- are taking non-steroidal anti-inflammatories (NSAIDs) e.g. Indometacin, aspirin. This is particularly important in the elderly or those with a history of ulcers.
- are middle aged or older and have new or recently changed heartburn or indigestion symptoms

If any of these points apply to you, do not take this medicine until you have talked to your doctor. You may need to be given a different medicine or the dose may need to be changed.

Using other medicines:
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal medicines. This is because Ranitidine tablets can affect the way some other medicines work. Also some other medicines can affect the way Ranitidine tablets work.

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

- Phenytoin, for epilepsy (fits)
- Diazepam, a sedative used for anxiety, seizures, insomnia etc
- Lidocaine, an anaesthetic
- Propranol, a beta blocker used to treat high blood pressure
- Procainamide, for heart rhythm problems
- Theophylline, for breathing problems
- Blood thinning medicines e.g. warfarin
- Glipizide, for lowering blood glucose
- Sucralfate, for treatment of peptic ulcer
- Atazanavir or delaviridine, for treating HIV infection
- Triazolam, for sleep problems
- Gefitinib, for lung cancer
- Ketoconazole, an anti fungal medicine.
- Midazolam is a medicine that may be given to you just before you have an operation. Tell the doctor you are taking ranitidine tablets before your operation in case he or she wants to give you midazolam.

Taking Ranitidine Tablets with food and drink
Ranitidine tablets may be taken before or after meals, as soon as you have symptoms.

Pregnancy and breast-feeding:
Like other over the counter drugs Ranitidine 75mg tablets should not be taken during pregnancy and breast-feeding without consulting a doctor or pharmacist.

Driving and using machines:
Ranitidine 75mg tablets have no known effects on the ability to drive or operate machinery.

3. HOW TO TAKE RANITIDINE FILM-COATED TABLETS

Adults (including the elderly) and children 16 years of age and over:
Swallow one tablet whole with a glass of water as soon as you have symptoms. If symptoms persist for more than one hour or return, take another tablet. Do not take more than two tablets in 24 hours

Do not take the tablets for more than 6 days is a row unless told to by your doctor. Talk to your doctor if your symptoms get worse or persist after 6 days treatment.

Not recommended for children under 16 years of age

If you take more Ranitidine film-coated tablets than you should:
If you have taken too much tell your doctor straight away. Take your tablet pack with you.

If you forget to take Ranitidine film-coated tablets:
Do not take a double dose to make up for forgotten individual doses. Take your next dose 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 tablets can cause side effects.

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

- 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.

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

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:

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

- Feeling confused or depressed
- Seeing or hearing unexplained things (hallucinations)
- Headache
- Dizziness
- Involuntary movement disorders
- Blurred vision
- Your small blood vessels can become swollen (known as 'vasculitis'). Signs of this can include a rash, swollen joints or kidney problems
- Diarrhoea
- Flushing or marks on your skin that look like targets
- Unexplained hair loss
- Painful or swollen joints or muscles
- Impotence
- Breast tenderness and/or breast enlargement
- Breast discharge

This section is continued overleaf →

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

- Liver enzyme changes which may have an effect on some medical tests
- Skin rash

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.

5. HOW TO STORE RANITIDINE TABLETS

Do not store above 25°C.

Keep out of the reach and sight 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. FURTHER INFORMATION

What Ranitidine film-coated tablets contain
The active substance is ranitidine hydrochloride (75mg).
The other ingredients are microcrystalline cellulose, magnesium stearate, hypromellose and titanium dioxide (E171).

What Ranitidine film-coated tablets look like and contents of the pack
Ranitidine 75mg Tablets are white, round and film coated with a "K" logo on one side and 75 on the other.

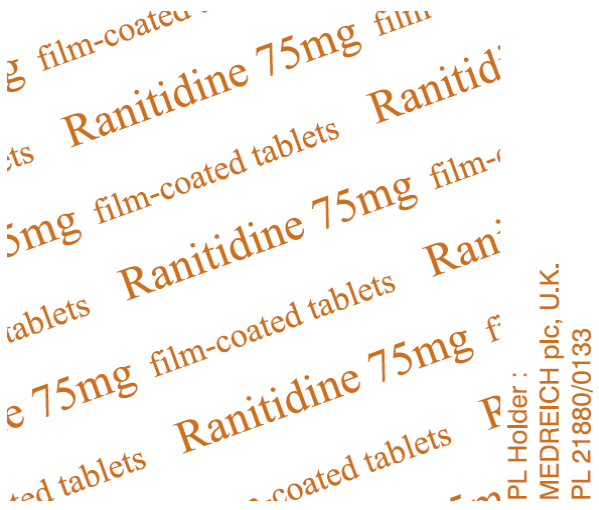
Ranitidine 75mg film-coated tablets come in packs of 6 and 12 tablets

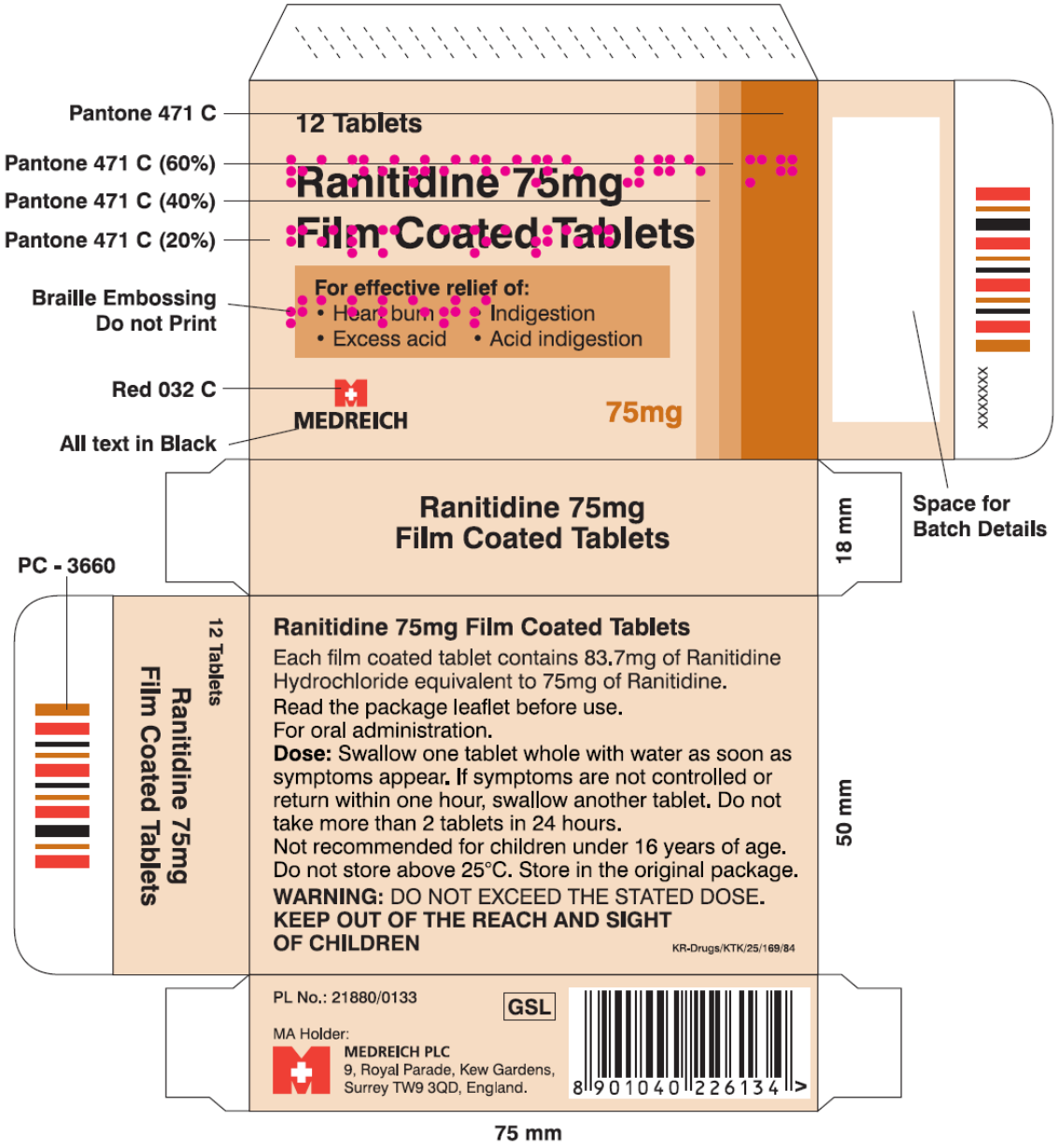
Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation holder, manufacturer and distributor is MEDREICH plc, 9, Royal Parade, Kew Gardens, Surrey TW9 3QD, England.

PL No.: 21880/0133
This package leaflet was last revised in June 2012.

GSL

LABELLING




Pantone 471 C
Pantone 471 C (60%)
Pantone 471 C (40%)
Pantone 471 C (20%)
Braille Embossing
Do not Print
Red 032 C
All text in Black
12 Tablets
Ranitidine 75mg
Film Coated Tablets
For effective relief of:
• Heartburn • Indigestion
• Excess acid • Acid indigestion
MEDREICH
75mg
XXXXXX
Space for
Batch Details
Ranitidine 75mg
Film Coated Tablets
18 mm
PC - 3660
12 Tablets
Ranitidine 75mg
Film Coated Tablets
Ranitidine 75mg Film Coated Tablets
Each film coated tablet contains 83.7mg of Ranitidine Hydrochloride equivalent to 75mg of Ranitidine.
Read the package leaflet before use.
For oral administration.
Dose: Swallow one tablet whole with water as soon as symptoms appear. If symptoms are not controlled or return within one hour, swallow another tablet. Do not take more than 2 tablets in 24 hours.
Not recommended for children under 16 years of age.
Do not store above 25°C. Store in the original package.
WARNING: DO NOT EXCEED THE STATED DOSE.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN
KR-Drugs/KTK/25/169/84
50 mm
PL No.: 21880/0133
GSL
MA Holder:
MEDREICH PLC
9, Royal Parade, Kew Gardens,
Surrey TW9 3QD, England.
8 901040 226134 >
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