RANITIDINE 75MG FILM COATED TABLETS
PL 17907/0028

UKPAR

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RANITIDINE 75MG FILM COATED TABLETS
PL 17907/0028

LAY SUMMARY

The MHRA granted Bristol Laboratories Ltd a Marketing Authorisation (licence) for the medicinal product Ranitidine 75mg film coated tablets (PL 17907/0028). This product is available on the general sale list (GSL) for the symptomatic relief of heartburn, indigestion, acid indigestion and hyperacidity.

Ranitidine 75mg film coated tablets contain the active ingredient ranitidine which is a H_2-blocker that prevents your stomach from producing too much acid.

The test product was considered to be equivalent to the original product Zantac 75 Relief (Glaxo Wellcome UK Ltd) based on the data submitted.

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

RANITIDINE 75MG FILM COATED TABLETS
PL 17907/0028

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a Marketing Authorisation for the medicinal product Ranitidine 75mg film coated tablets to Bristol Laboratories Ltd on 06 March 2007. The product is on the general sales list.

The application was submitted as an abridged application according to Article 10.1 of Directive 2001/83/EC, claiming to be a generic product of Zantac 75 Relief (Glaxo Wellcome UK Ltd). The reference product has been authorised in the UK since September 1994 and so the 10-year period of data exclusivity has expired.

The product contains the active ingredient ranitidine, as ranitidine hydrochloride, and is indicated for the symptomatic relief of heartburn, indigestion, acid indigestion and hyperacidity.

Ranitidine is an H_2-receptor antagonist. It inhibits basal and stimulated secretion of gastric acid, reducing both the volume and the acid and pepsin content of the secretion.

The application was submitted at the same time as those for Ranitidine 150mg film coated tablets (PL 17907/0029) and Ranitidine 300mg film coated tablets (PL 17907/0030) and depends on the bioequivalence study that compares the applicant's 300mg strength with the reference product Zantac Tablets 300mg (GlaxoSmithKline, UK).

PHARMACEUTICAL ASSESSMENT

COMPOSITION

The product is formulated as a film-coated tablet containing 75mg of the active pharmaceutical ingredient ranitidine, as ranitidine hydrochloride. The excipients present are microcrystalline cellulose, magnesium stearate, hypromellose and titanium dioxide.

Ranitidine 75mg film coated tablets are presented in aluminium-foil sealed polyamide/Aluminium/PVC blisters in packs of 6 or 12 tablets.

DRUG SUBSTANCE

Ranitidine Hydrochloride

All aspects of the manufacture and control of ranitidine hydrochloride are supported by EDQM Certificates of Suitability. These certificates are accepted as confirmation of the suitability of ranitidine hydrochloride for inclusion in this medicinal product.

Stability data have been generated supporting a retest period of 2 years from one supplier and 3 years from the other supplier when stored in the proposed packaging.

DRUG PRODUCT

Other ingredients

All excipients used in the manufacture of the tablets are routinely tested for compliance with current relevant international standards.

Satisfactory certificates of analysis have been provided for all excipients.

No excipients used contain material of animal or human origin.

Dissolution profiles

Dissolution profiles for the drug product (Ranitidine 75mg film coated tablets) were found to be similar to the reference product (Zantac 75 Relief).

Impurity profiles

Data was provided for the drug product and reference product. No known or unknown impurities were detected.

Manufacture

A full description and a detailed flow-chart of the manufacturing method including in-process control steps has been provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out on batches of the 75 mg strength. The results are satisfactory.

Finished product specification
The proposed finished product specification is acceptable and the analytical methods used have been suitably validated. Batch analysis data have demonstrated compliance with the proposed release specification. Suitable reference standards were used.

Container Closure System
Satisfactory specifications and certificates of analysis have been provided for the packaging components. All primary product packaging complies with EU legislation regarding contact with food.

Stability
Finished product stability data support the proposed shelf-life of 2 years with storage conditions "Do not store above 25°C. Store in the original package."

Bioequivalence/bioavailability
Refer to the clinical assessment report.

SPC, PIL and Labels
The SPC, PIL and labels are pharmaceutically acceptable.

The marketing authorisation holder has provided a commitment to update the marketing authorisation with a patient information leaflet in compliance with Article 59 of Council Directive 2001/83/EC and that the leaflet shall reflect the results of consultation with target patient groups, no later than 01 July 2008.

CONCLUSION

The proposed product has been shown to be a generic product of the reference product and has met the requirements with respect to qualitative and quantitative content of the active substance. Similar dissolution profiles have been demonstrated for the proposed and reference product.

It is recommended that a Marketing Authorisation should be granted for this application.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

INTRODUCTION AND BACKGROUND

These are generic abridged applications for film-coated tablets containing 75mg ranitidine as ranitidine hydrochloride.

The application is submitted under the provisions of Directive 2001/83/EC Article 10.1 as amended, claiming that Ranitidine 75mg film coated tablets is a generic product of Zantac 75 Relief (Glaxo Wellcome UK Ltd) which has been authorised in the UK for more than 10 years.

Ranitidine is an H_2 antagonist gastric antisecretory drug and is well characterised in the literature.

INDICATIONS

The following indications have been approved:

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

DOSE AND DOSE SCHEDULE

The proposed dose and dose schedule for these products to be used for the above indications are consistent with those of the reference products.

PHARMACODYNAMICS

No new data were submitted. The pharmacodynamics of ranitidine are well described. It is a specific, rapidly acting histamine H_2-antagonist which inhibits basal and stimulated secretion of gastric acid, reducing both the volume and the acid and pepsin content of the secretion.

PHARMACOKINETICS

No new data were submitted. The pharmacokinetics of ranitidine are well described. Absorption of ranitidine after oral administration is rapid and peak plasma concentrations are usually achieved within two hours of administration. Food or antacids do not significantly impair absorption and the expert report provides satisfactory reassurance that absorption is linear over the therapeutic range. The elimination half-life of ranitidine is approximately two hours. Ranitidine is excreted via the kidneys mainly as the free drug and, in minor amounts, as smaller quantities of S-oxide and desmethyl ranitidine. The 24 hour urinary recovery of free ranitidine and its metabolites is about 40% with orally administered drug.

BIOEQUIVALENCE

A single bioequivalence study was presented for the 300mg tablet, carried out in compliance with Good Clinical Practice.

The reference product used in the study was Zantac Tablets 300mg manufactured by GlaxoSmithKline, UK. The test product used was Ranitidine 300mg film coated tablets.

In this comparative, randomised, two-way, two-period, single dose crossover study, 24 healthy fasted male and female volunteers received 300mg orally of the applicant's test product and the reference product. Serum drug levels were measured hourly for the first 4 hours following dosing then at 6, 8, 10, 12 and 24 hours. The schedule was appropriate for accurate determination of AUC_{inf} but the hourly sampling interval around C_{max} is inadequate to estimate this parameter with any accuracy. The washout period of 7 days between phases was sufficiently long given the short half life of the drug (approximately 2.5 hours).

Results

No subjects discontinued the study. Data for AUC_t, AUC_{inf} and C_{max} were analysed by ANOVA. T_{max} was analysed non-parametrically. Bioequivalence results for test/reference ratios with 90% Confidence Intervals are as follows:

	Test	**Reference**	**Test/Reference ratio**
AUC_t	5727	5899	0.98 (0.86 – 1.04)
C_{max}	1177	1254	0.94 (0.81 – 1.08)
T_{max}	3.33 hrs	2.92 hrs	

The inability of the sampling interval to accurately estimate C_{max} is not considered to be a major deficiency as C_{max} is not a very important parameter for this drug and there is no indication that the two products performed significantly differently in their rate of absorption. Bioequivalence has been satisfactorily demonstrated for the 300mg preparation, in accordance with CPMP criteria. As the formulations for the 300mg and 75mg strengths are linear and the products show comparable dissolution profiles, exemption for another bioequivalence study for the 75mg strength is justified.

CLINICAL EFFICACY

No new efficacy data were presented in this application and none are required.

CLINICAL SAFETY

No new safety data were presented in this application and none are required. There were no significant adverse events in the bioequivalence study and the literature review in the expert report did not identify any new safety issues.

CLINICAL EXPERT REPORT

The clinical expert report has been written by an appropriately qualified medical doctor. It is an adequate summary of the clinical data provided in the dossier.

SPC, PIL and LABELS

The SPC, PIL and labels are acceptable.

CONCLUSIONS

The clinical efficacy and safety of ranitidine is well known from its use in clinical practice. No new data were submitted and this is acceptable. Bioequivalence of the product has been shown. Considering the relative composition of the 75 and 300mg products, *in vitro* dissolution profiles and ranitidine pharmacokinetics, extrapolation of the outcome of the bioequivalence study to the lower strength product is justified. A Marketing Authorisation should be granted for this application.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of Ranitidine 75mg film coated tablets are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

Bioequivalence has been demonstrated between the applicant's Ranitidine 300mg film coated tablets and Zantac Tablets 300mg (GlaxoSmithKline, UK).

No new or unexpected safety concerns arise from this application.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The bioequivalence study supports the claim that the applicant's product and the reference product are interchangeable. The risk benefit is, therefore, considered to be positive.

RANITIDINE 75MG FILM COATED TABLETS
PL 17907/0028

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Marketing Authorisation application on 24 June 2002.

2 Following standard checks and communication with the applicant, the MHRA considered the application valid on 23 August 2002.

3 Following assessment of the application, the MHRA requested further information relating to the quality dossier on 10 January 2003, 27 June 2003, 04 August 2004, 22 December 2004, 21 August 2006 and 29 November 2006 and further information relating to the clinical dossier on 10 January 2003.

4 The applicant responded to the MHRA's requests, providing further information on 28 March 2003, 23 April 2004, 14 September 2004, 28 November 2005, 29 November 2006 and 13 December 2006 for the quality sections, and again on 28 March 2003 for the clinical sections.

5 The application was determined on 06 March 2007.

RANITIDINE 75MG FILM COATED TABLETS
PL 17907/0028

STEPS TAKEN AFTER AUTHORISATION – SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ranitidine 75mg film coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains ranitidine 75 mg (as the hydrochloride).

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film coated tablets.

White to almost white, circular, biconvex, film coated tablets embossed with “BL” on one side and “75” on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

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

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.

4.2 Posology and method of administration

The tablets have to be swallowed whole.

Adults (Including the Elderly) and children 16 years of age and older:

Swallow one Ranitidine 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 contraindicated for people known to be hypersensitive to the drug or any of the ingredients of Ranitidine Film Coated tablets.

4.4 Special warnings and precautions for use

Malignancy: The possibility of malignancy should be excluded before commencement of therapy in patients with gastric ulcer as treatment with ranitidine may mask symptoms of gastric carcinoma.

Regular supervision of patients who are taking non-steroidal anti-inflammatory drugs concomitantly with ranitidine is recommended, especially in the elderly and in those with a history of peptic ulcer.

Ranitidine should be avoided in patients with a history of acute porphyria.

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

4.5 Interaction with other medicinal products and other forms of interaction

Ranitidine does not inhibit the hepatic Cytochrome P450-linked mixed function oxygenase system at therapeutic doses.

Accordingly, ranitidine does not potentiate the actions of drugs, which are inactivated by this enzyme; these include diazepam, lidocaine, phenytoin, propranolol, theophylline and warfarin.

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, Ranitidine Film Coated Tablets should not be taken during pregnancy without consulting a doctor or pharmacist. Ranitidine is also excreted in human breast milk and women who are breast-feeding will be advised to speak to their doctor before taking Ranitidine Film Coated 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).

Blood & lymphatic system Disorders

Very Rare: Blood count changes (leucopenia, thrombocytopenia). These are usually reversible. Agranulocytosis or pancytopenia, sometimes with marrow hypoplasia or marrow aplasia.

Immune System Disorders

Rare: Hypersensitivity reactions (urticaria, angioneurotic oedema, fever, bronchospasm, hypotension and chest pain).

Very Rare: Anaphylactic shock

These events have been reported after a single dose.

Psychiatric Disorders

Very Rare: Reversible mental confusion, depression and hallucinations.

These have been reported predominantly in severely ill and elderly patients.

Nervous System Disorders

Very Rare: Headache (sometimes severe), dizziness and reversible involuntary movement disorders.

Cardiac Disorders

Very Rare: As with other H_2 receptor antagonists bradycardia and A-V Block.

Vascular Disorders

Very Rare: Vasculitis.

Gastrointestinal Disorders

Very Rare: Acute pancreatitis. Diarrhoea.

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.

Skin and Subcutaneous Tissue Disorders

Rare: Skin Rash.

Very Rare: Erythema multiforme, alopecia.

Musculoskeletal and Connective Tissue Disorders

Very Rare: Musculoskeletal symptoms such as arthralgia and myalgia.

Renal and Urinary Disorders

Very rare: Acute interstitial nephritis.

Reproductive System and Breast Disorders

Very Rare: Reversible impotence. Breast symptoms in men.

4.9 Overdose

Ranitidine 75 mg film coated tablets is very specific in action and accordingly no particular problems are expected following overdosage with the drug. 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 H_2-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 a single 75mg dose suppresses gastric acid secretion for up to twelve hours.

Clinical studies have shown that Ranitidine 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 2-3 hours after 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 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 H_2 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 (E171)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Polyamide/ Aluminium/PVC/Aluminium blisters containing 6 tablets. Blisters packaged into outer container to give total of 6 or 12 tablets.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Bristol Laboratories Limited

Unit 3, Canalside, Northbridge Road,

Berkhamsted, Herts, HP4 1EG

UK.

8 MARKETING AUTHORISATION NUMBER(S)

PL 17907/0028

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/03/2007

10 DATE OF REVISION OF THE TEXT

06/03/2007

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you start to take this medicine. If after reading this leaflet, you have any questions or are not sure about anything, ask your doctor or pharmacist. Keep this leaflet; you may want to read it again.

The name of this medicine is
RANITIDINE 75 MG FILM-COATED TABLETS

The tablets are film-coated and contain 75 mg of the active ingredient ranitidine hydrochloride. The tablets also contain microcrystalline cellulose, magnesium stearate, hypromellose and titanium dioxide (E171)
The product licence holder and manufacturer is Bristol Laboratories Ltd, Unit 3, Canalside, Northbridge Road, Berkhamsted, Herts, HP4 1EG, UK.

What the tablets are and what they are used for

The active ingredient ranitidine belongs to a group of medicines called 'H2-blockers'. It works by preventing your stomach from producing too much acid.
The tablets are white to almost white, circular, biconvex, film coated tablets embossed with “BL” on one side and “75” on the other.
Ranitidine 75mg Film Coated Tablets comes in blister packs of 6 and 12 tablets.
Ranitidine 75mg Tablets treat indigestion and heartburn for up to 12 hours. One of the most common causes of indigestion and heartburn is excess acid in the stomach.

Before taking your medicine

Please get your pharmacist or doctors' advice before taking these tablets if:

- you are allergic to any of the ingredients of Ranitidine 75 mg Tablets listed above
- you have difficulty swallowing
- you are pregnant, trying to become pregnant or breast feeding
- you suffer from a rare condition called porphyria
- you have persistent stomach pains
- you have unintended weight loss
- you are middle aged or older with new or recently changed indigestion symptoms
- you are taking any medicines, including 'pain killers' of the class known as non-steroidal anti-inflammatory drugs (NSAIDS, such as aspirin or ibuprofen) regularly. This advice is even more important if you are elderly.

Taking your medicine

Adults (including the elderly) and children 16 years of age and older:
Swallow one Ranitidine 75mg Tablet whole, with a drink of water, as soon as you have symptoms.
If symptoms persist for more than one hour, take another tablet. Do not take more than two tablets in 24 hours.
Do not give to children under 16 years of age.
Important warning If after 6 days you still have symptoms, you should not

keep treating yourself with these tablets without taking the advice of a pharmacist or doctor. You may have another medical condition that needs different treatment.
If your symptoms get worse or are no better with this medicine, please consult your doctor.
If you take too much:
If you have taken too many tablets, you must obtain immediate assistance from your doctor or hospital casualty department.

Possible Side -Effects

Most people taking Ranitidine 75mg Tablets find they cause them no problems. Some side effects are even less likely when you only take the tablets occasionally. As with all medicines some people may be allergic to them but this is very rare with Ranitidine 75mg tablets.
The usual allergic reaction is a skin rash or sometimes swelling of the eyelids, face or lips and some people have noticed sudden wheeziness, pain or tightness of the chest or have felt faint feverish, or collapsed.
In this case stop taking the tablets and tell your doctor immediately.
Headaches, dizziness, hallucinations, depression, and confusion have been reported rarely. In addition, there have been rare reports of uncontrolled movements, this effect is usually reversible and should get better once you stop taking this medicine. Even more rarely the following have been reported in association with using the medicine:

- Aches and pains in muscles and joints
- Inflammation of the liver (with or without yellowing of the skin)
- Pancreatitis (stomach pain)
- Slow or irregular heart beat
- Inflammation of blood vessels (vasculitis)
- Hair loss (alopecia)

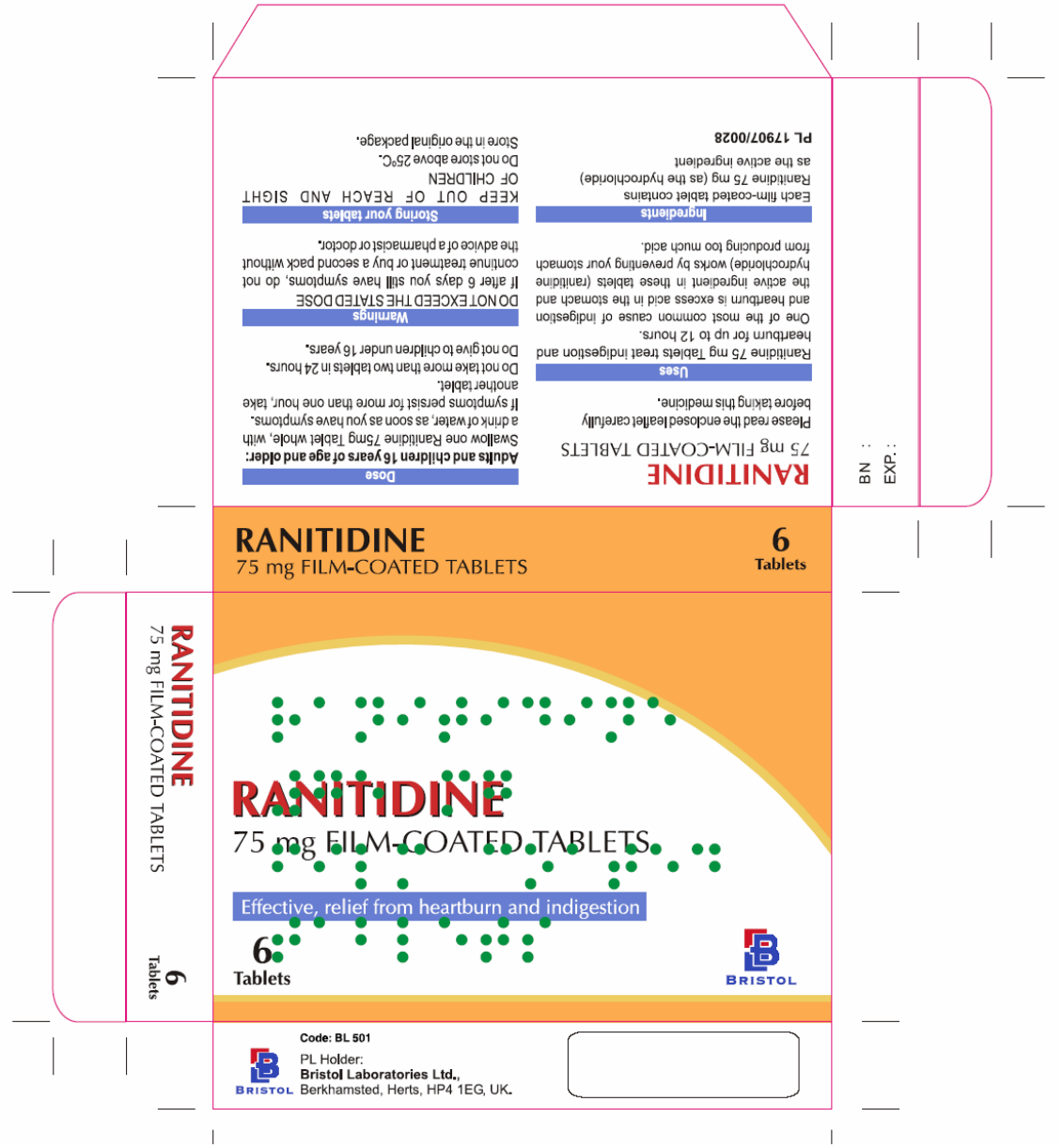
In men, breast tenderness and/ or breast enlargement; interference with sexual function (impotence) have been reported very rarely. This interference with sexual function is normally reversible and should get better once you stop taking this medicine.
The results of laboratory tests on your liver may be altered.
Tests sometimes show upsets to blood counts only very rarely causing unusual tiredness, shortness of breath or a tendency to bruise or get infections.
If you feel unwell or have any unusual symptoms you do not understand, stop taking the tablets and tell your doctor or pharmacist.

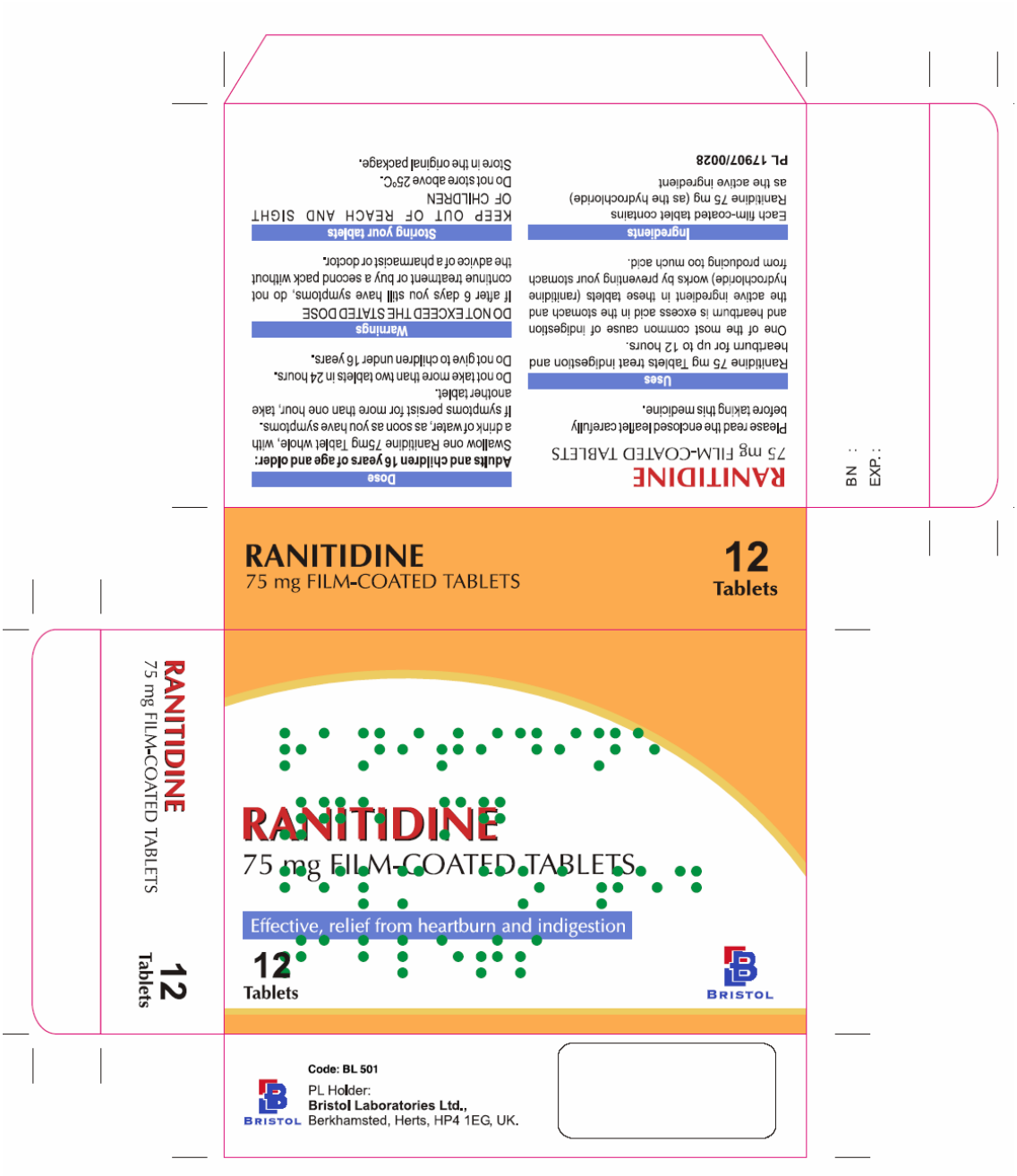
Storing your medicine

Keep out of the reach and sight of children.
Do not store above 25°C. Store in the original package (blister carton) to protect from moisture.
Do not use the tablets after the expiry date shown on the carton.

This leaflet was last revised October 2005.

LABELLING


RANITIDINE
75 mg FILM-COATED TABLETS
6
Tablets
RANITIDINE
75 mg FILM-COATED TABLETS
Effective, relief from heartburn and indigestion
6
Tablets
BRISTOL
Code: BL 501
PL Holder:
Bristol Laboratories Ltd.,
Berkhamsted, Herts, HP4 1EG, UK.
RANITIDINE
75 mg FILM-COATED TABLETS
6
Tablets
BN :
EXP. :
Dose
Adults and children 16 years of age and older:
Swallow one Ranitidine 75mg Tablet whole, with a drink of water, as soon as you have symptoms.
If symptoms persist for more than one hour, take another tablet.
Do not take more than two tablets in 24 hours.
Do not give to children under 16 years.
Warnings
DO NOT EXCEED THE STATED DOSE
If after 6 days you still have symptoms, do not continue treatment or buy a second pack without the advice of a pharmacist or doctor.
Storing your tablets
KEEP OUT OF REACH AND SIGHT OF CHILDREN
Do not store above 25°C.
Store in the original package.
Ingredients
Each film-coated tablet contains
Ranitidine 75 mg (as the hydrochloride)
as the active ingredient
PL 17907/0028
Uses
Ranitidine 75 mg Tablets treat indigestion and heartburn for up to 12 hours.
One of the most common cause of indigestion and heartburn is excess acid in the stomach and the active ingredient in these tablets (ranitidine hydrochloride) works by preventing your stomach from producing too much acid.


RANITIDINE
75 mg FILM-COATED TABLETS
12
Tablets
RANITIDINE
75 mg FILM-COATED TABLETS
Effective, relief from heartburn and indigestion
12
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as the active ingredient
PL 17907/0028
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Do not store above 25°C.
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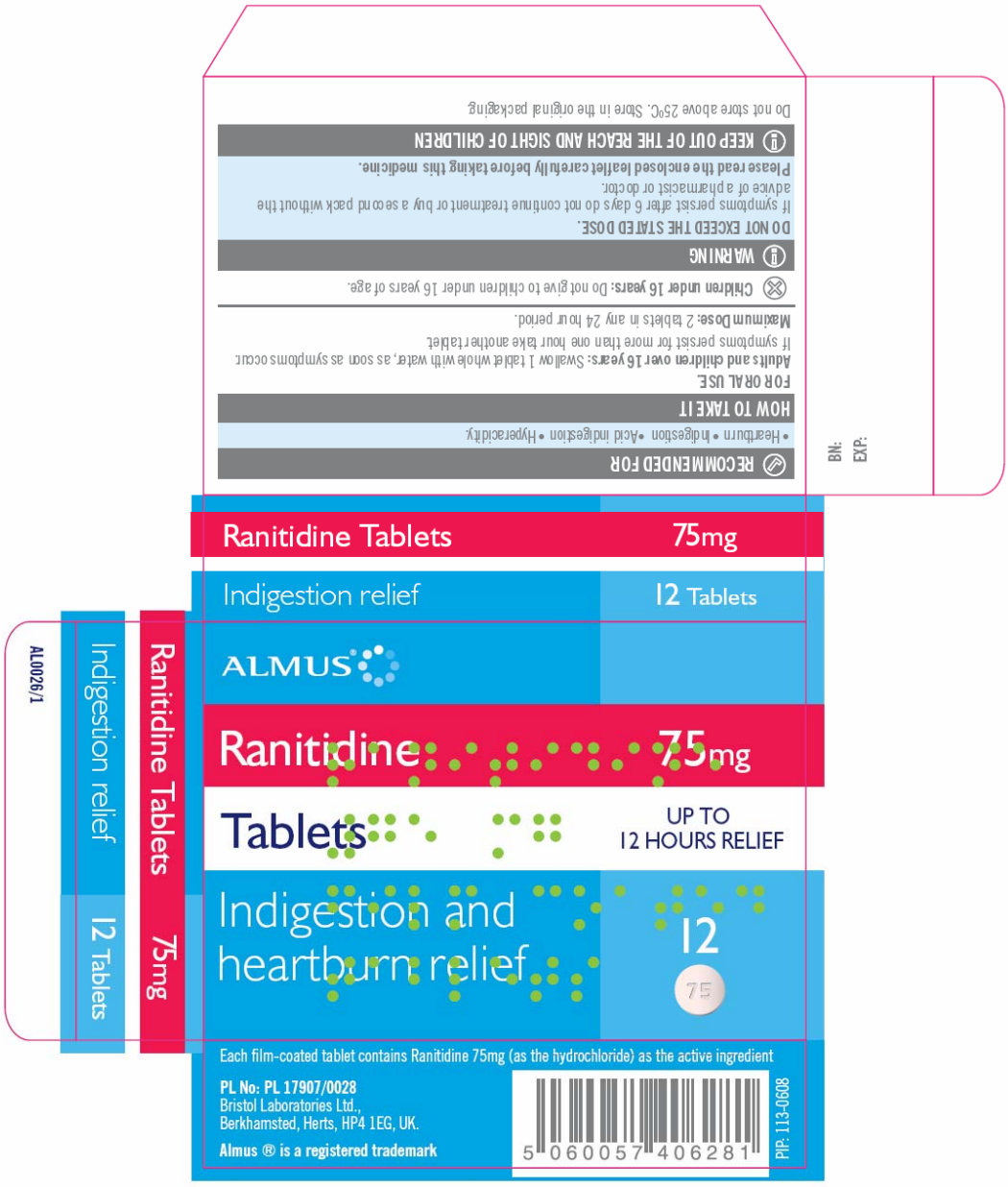
BN :
EXP.:


Ranitidine 75 mg
Film-coated tablets
Each film coated tablet contains
Ranitidine 75 mg
(as the hydrochloride)
PL Holder
Bristol Laboratories Ltd.
Code: BL 501


RECOMMENDED FOR
• Heartburn • Indigestion • Acid indigestion • Hyperacidity
HOW TO TAKE IT
FOR ORAL USE
Adults and children over 16 years: Swallow 1 tablet whole with water, as soon as symptoms occur.
If symptoms persist for more than one hour take another tablet.
Maximum Dose: 2 tablets in any 24 hour period.
Children under 16 years: Do not give to children under 16 years of age.
WARNING
DO NOT EXCEED THE STATED DOSE.
If symptoms persist after 6 days do not continue treatment or buy a second pack without the advice of a pharmacist or doctor.
Please read the enclosed leaflet carefully before taking this medicine.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN
Do not store above 25°C. Store in the original packaging
BN:
EXP:
Ranitidine Tablets 75mg
Indigestion relief
12 Tablets
ALMUS
Ranitidine 75mg
Tablets
UP TO 12 HOURS RELIEF
Indigestion and heartburn relief
12
75
Each film-coated tablet contains Ranitidine 75mg (as the hydrochloride) as the active ingredient
PL No: PL 17907/0028
Bristol Laboratories Ltd.,
Berkhamsted, Herts, HP4 1EG, UK.
Almus ® is a registered trademark
5 060057 406281
PIP: 113-0608
Ranitidine Tablets 75mg
Indigestion relief
12 Tablets
AL0026/1