Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

UKPAR

Lansoprazole 15 mg gastro-resistant capsules, hard
Lansoprazole 30 mg gastro-resistant capsules, hard

(lansoprazole)

UK licence Number: PL 00289/0675-0676

MR number: UK/H/0884/001-002/MR

TEVA UK LIMITED

LAY SUMMARY

Lansoprazole 15 mg and 30 mg gastro-resistant capsules, hard (lansoprazole)

This is a summary of the Public Assessment Report (PAR) for Lansoprazole 15 mg and 30 mg gastro-resistant capsules, hard (PL 00289/0675-0676; UK/H/0884/001-002/MR). It explains how Lansoprazole 15 mg and 30 mg gastro-resistant capsules, hard was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product. The product will be referred to as Lansoprazole capsules throughout the remainder of this summary.

For practical information about using Lansoprazole capsules, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lansoprazole capsules and what is it used for?
Lansoprazole capsules are 'generic medicines'. This means that Lansoprazole capsules are similar to 'reference medicines' already authorised in the European Union (EU) called Lanzor 15mg and 30mg Magensaftresistent Kapseln.

This medicine is used:

- To treat ulcers in the duodenum and stomach (diagnosed through gastroscopy or X-ray).

- To treat inflammation of the gullet caused by reflux of stomach acid into the gullet (reflux oesophagitis).

- As long-term treatment to prevent a recurrence of inflammation of the gullet due to reflux of stomach acid.

- To remove the bacterium *Helicobacter pylori* together with suitable antibiotics in the treatment of ulcers in the stomach or duodenum (eradication therapy) and to prevent the recurrence of ulcers in patients with *Helicobacter pylori*-related ulcers in the stomach and intestines.

- In the treatment of Zollinger-Ellison syndrome (ulcer formation in the stomach and duodenum, due to increased production of a hormone which secretes stomach acid, caused by a certain type of tumour).

- To treat and prevent ulcers in the duodenum and stomach caused by the use of non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or aspirin.

How does Lansoprazole capsules work?
The active substance in Lansoprazole capsules is lansoprazole. Lansoprazole is a medicine which reduces the amount of acid made by the stomach (selective proton pump inhibitor).

How is Lansoprazole capsules used?
The pharmaceutical form of Lansoprazole capsules is gastro-resistant tablets and the route of administration is oral.

The patient should always take this medicine exactly as his/her doctor has advised. The patient should check with his/her doctor or pharmacist if unsure.

Lansoprazole capsules are swallowed whole with sufficient liquid (e.g. a glass of water). If the capsules are difficult to swallow the patient's doctor may advise on alternative ways to take this medicine. The capsules may be opened but the granules inside may not be chewed or crushed because this will stop them from working properly. Lansoprazole capsules should be taken on an empty stomach (at least 30 minutes before meals).

A patient taking this medicine once a day, should try to take it at the same time each day. The patient may get best results if they take it first thing in the morning. If they are taking their medicine twice a day, they should have the first dose in the morning and the second dose in the evening.

The dose of this medicine depends on the patient's condition. The doctor will sometimes prescribe a different dose and will tell their patient how long the treatment will last.

Please read Section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

This medicine can only be obtained with a prescription.

What benefits of Lansoprazole capsules have been shown in studies?
Because Lansoprazole capsules are a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicines, Lanzor 15mg and 30mg Magensaftresistent Kapseln . Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Lansoprazole capsules?
Because Lansoprazole capsules are generic medicines, its possible side effects are taken as being the same as those of the reference medicine, Lanzor 15mg and 30mg Magensaftresistent Kapseln.

For the full list of all side effects reported with Lansoprazole capsules, see Section 4 of the package leaflet available on the MHRA website.

For the full list of restrictions, see the package leaflet.

Why is Lansoprazole capsules approved?
It was concluded that, in accordance with EU requirements, Lansoprazole capsules has been shown to have comparable quality and to be bioequivalent to Lanzor 15mg and 30mg Magensaftresistent Kapseln. Therefore, the MHRA decided that, for Lansoprazole capsules, the benefits are greater than the risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Lansoprazole capsules?
Known side effects are continuously monitored. Furthermore, new safety signals reported by patients and healthcare professionals will be monitored and reviewed continuously, as well.

Other information about Lansoprazole capsules
On 18th September 2007, Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, The Netherlands, Norway, Poland, Portugal, Slovak Republic, Spain and Sweden granted Teva UK Limited Marketing Authorisations (licences) for the medicinal products Teva Lansoprazole 15mg and 30mg Gastro-resistant Capsules (PL 00289/0675-6; UK/H/0884/001-2/MR). These licences were granted by Mutual Recognition Procedure (MRP), with the UK as reference member state (RMS). National licences were originally granted in the UK on 9th December 2005.

The full PAR for Lansoprazole capsules follows this summary.

For more information about treatment with Lansoprazole capsules, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in December 2017.

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I INTRODUCTION

Please note that the below scientific discussion consists of the original assessment of this product licence, plus a summary of key post approval changes at the end of this introduction section to improve the accuracy of this Public Assessment Report.

Based on the review of the data on quality, safety and efficacy, Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, The Netherlands, Norway, Poland, Portugal, Slovak Republic, Spain and Sweden considered that the applications for Lansoprazole 15mg and 30mg Gastro-resistant Capsules, Hard (PL 00289/0675-6; UK/H/0884/001-2/MR) could be approved.

The products are prescription-only medicines for the treatment of acid-related disorders of the upper gastro-intestinal tract, with the benefit of rapid symptom relief. Lansoprazole is also effective in combination with antibiotics in the eradication of Helicobacter pylori (H. pylori).

These applications were made under the Mutual Recognition Procedure (MRP), with the UK as reference member state (RMS). National licences had previously been granted in the UK on 9th December 2005. The legal basis for these applications was Article 10.1 of 2001/83 EC, as amended, claiming to be generic medicinal products of Lanzor 15mg and 30mg Magensaftresistent Kapseln (Takeda, Denmark) which were granted UK licences over 10 years ago.

The active ingredient, lansoprazole, is a proton pump inhibitor, which reduces gastric acidity by blocking the hydrogen-potassium adenosine tri-phosphatase enzyme system (the 'proton pump') of the gastric parietal cell. It is used to treat gastro-oesophageal reflux disease, ulcers, acid-related dyspepsia and as an adjuvant in the eradication of H. pylori.

No new preclinical studies were conducted, which is acceptable given that the applications were based on being generic medicinal products of originator products that have been licensed for over 10 years. No new clinical studies were conducted, which is acceptable given that the applications were based on being generic medicinal products of originator products that have been licensed for over 10 years. The bioequivalence studies were carried out in accordance with Good Clinical Practice (GCP).

The RMS has been assured that acceptable standards of GMP are in place for these product types at all sites responsible for the manufacture and assembly of this product prior to granting authorisation. For manufacturing sites outside the community, the RMS has accepted copies of current GMP Certificates or satisfactory inspection summary reports, 'close-out letters' or 'exchange of information' issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards of GMP are in place at those non-Community sites.

At the end of the procedure, these applications were referred to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) by some of the Concerned Member States (CMS) for the following: A serious public health concern was raised by three member states who considered that bioequivalence in the fed state had not been established for registration in the national market concerned. Bioequivalence had been demonstrated only under fasting conditions. At the CMD(h) meeting, held 11th-12th December 2006, the RMS presented its view and the applicant's written and oral explanation were discussed. The applicant explained the absence of any potential risk to public health resulting from the findings of the fed study (90% CI for AUC_{inf} 78-110%). Lansoprazole's bioavailability is not only markedly reduced (by approximately 70%) when taken with food, but its absorption, in the presence of food, can be quite erratic as shown by the large intra-subject variability (70-82%). This is particularly so following a high fat high

calorie meal, as is the case with the applicant's fed study. The SmPC and PIL were amended to make it clear that the product should be administered on an empty stomach. The final proposed wording was: The capsules are swallowed whole with liquid. The capsules may be emptied, but the contents may not be chewed or ground. Concomitantly taken food slows down and reduces the absorption of lansoprazole. This medicine has the best effect when taken into empty stomach.

This is consistent with the outcome of the Article 29 referral for generic lansoprazoles (which was converted to a Commission Decision on 21st February 2006).

However, the proposal was not acceptable to the CMS and the application was, therefore, referred to Committee for Medicinal Products for Human Use (CHMP) for arbitration and discussed at their meeting on 18th-21st June 2007. The CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, was of the opinion that the benefit/risk ratio is favourable for these products, that the objections raised by the Czech Republic, Spain and Portugal should not prevent the granting of Marketing Authorisations, and that the valid SPC, labelling and PIL were the final versions achieved during the CMD(h) procedure. A positive opinion was adopted by consensus on 21st June 2007.

Summary of key post-approval changes:
The following post-approval variations have been granted for these licences:

1. To reduce the shelf life of the product on blisters from 24 to 18 months-section 6.3 (shelf-life) of the SPC is updated, granted 9 December 2008 (PL 00289/0676 – 0012).
2. To add HDPE bottles with PP closure and desiccant as an additional package in the same pack sizes as the exiting blisters (7, 14, 15, 28, 30, 50, 56, 84, 98 and 100 gastro-resistant capsules, shelf life 24 months) to the product licence, granted 5 February 2008 (PL 00289/0676-0013).

II QUALITY ASPECTS

II.1 Introduction

Lansoprazole 15 mg gastro-resistant capsules, hard contains 15 mg of lansoprazole.

Lansoprazole 30 mg gastro-resistant capsules, hard contains 30 mg of lansoprazole.

Other ingredients consist of the pharmaceutical excipients sugar spheres (composed of sucrose, maize and starch), hypromellose, talc, magnesium carbonate, methacrylic acid ethylacrylate copolymer, triethyl citrate, titatnium dioxide, capsule shells and ink. The capsules shells are composed of titanium dioxide (E171), red iron oxide (E172), gelatin, brilliant blue (E133 – 15mg Capsules only) and black iron oxide (E172 – 30mg Capsules only). The ink is composed of shellac, black iron oxide (E172) and propylene glycol.

Both capsule strengths are packaged in aluminium blisters, in pack sizes of 7 (30mg only), 14, 15, 28, 30, 50, 56, 84, 98 and 100 gastro-resistant capsules.

Satisfactory specifications and certificates of analysis have been provided for the packaging components.

Not all pack sizes may be marketed, however, the marketing authorisation holder has agreed to provide mock-ups of any pack size to the relevant regulatory authorities before marketing.

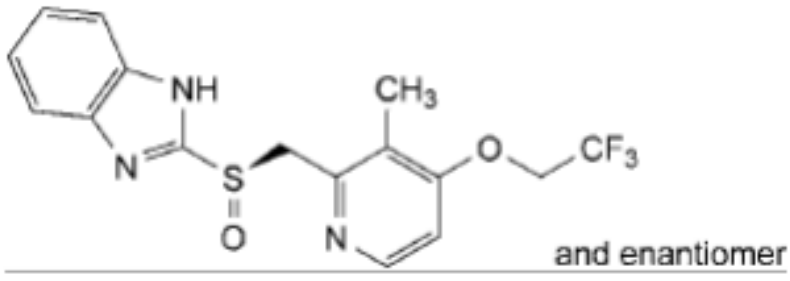
All primary product packaging complies with the current requirements. Satisfactory specifications and Certificates of Analysis have been provided for all packaging components.

II.2 DRUG SUBSTANCES

Lansoprazole

Chemical Name: 2-[[[3-methyl-4-(2, 2, 2-trifluoroethoxy)- pyridine-2-yl]methyl]sulfinyl benzimidazole
2-(2-benzimidazolylsulphinylmethyl)-3-methyl-4-(2, 2, 2-trifluoroethoxy)-2-pyridine

Structure:



Molecular Formula: $C_{16}H_{14}F_3N_3O_2.S$

Molecular Mass: 369.4

Appearance: White or brownish powder

Solubility: -. Practically insoluble in water, soluble in anhydrous ethanol, very

	slightly soluble in acetonitrile
Chirality:	Lansoprazole has a chiral centre, but is manufactured as a racemic mixture.

Synthesis of the drug substance from the designated starting materials has been adequately described, and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents, and these are supported by relevant certificates of analysis.

All potential known impurities have been identified and characterised.

Appropriate proof of structure has been supplied for the active pharmaceutical ingredient.

An appropriate specification is provided for the active substance lansoprazole. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. Batch analysis data are provided and comply with the proposed specification.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines concerning contact with food.

Appropriate stability data have been generated to support a suitable retest period when stored in the proposed packaging.

II.3 DRUG PRODUCT

Pharmaceutical development

The aim of the development programme was to obtain a capsule with enteric-coated granules containing qualitatively and quantitatively the same drug substance as the comparator products already on the market and with sufficient bioavailability to be considered as generic medicinal products of these.

A suitable product development section was submitted.

Comparative assay and impurity profiles have been provided for the test products and reference products from various EU countries.

All excipients comply with their respective European Pharmacopoeia monograph, with the exception of brilliant blue, black iron oxide and red iron oxide (which comply with suitable in-house specifications). Satisfactory certificates of analysis have been provided for all excipients.

With the exception of gelatin, none of the excipients used contain materials of animal or human origin. Suitable EDQM TSE Certificates of Suitability have been provided for all suppliers of gelatin.

No genetically modified organisms (GMO) have been used in the preparation of this product.

Manufacture of the product

A description and flow-chart of the manufacturing method has been provided.

Satisfactory batch formulae have been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results.

Finished Product Specification
The finished product specifications proposed for both release and shelf life are acceptable, and provide an assurance of the quality and consistency of the finished product. The analytical methods used have been suitably validated. Batch analysis and stability data have demonstrated compliance with the proposed release and shelf-life specification.

All impurities have been suitably characterised.

Stability
All stability studies were conducted in-line with ICH requirements. Stability data provided support a shelf-life of 2 years) for both strengths, with the storage conditions: 'Do not store above 25°C. Store in original package.' Suitable post approval stability commitments have been given to follow-up the current batches and to place the first three commercial batches on stability.

Reference Standards or Materials
Satisfactory certificates of analysis have been provided for any working standards used.

Bioequivalence/Bioavailability
Satisfactory Certificates of Analysis have been provided for the test and reference batches used in the bioequivalence study. Bio-analytical methods used have been satisfactorily validated.

Expert Report
The Pharmaceutical Expert Report has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical parts of the dossier.

II.4 Discussion on chemical, pharmaceutical and biological aspects

It is recommended that Marketing Authorisations are granted for these applications.

The requirements for essential similarity of the proposed and reference products have been met with respect to qualitative and quantitative content of the active substance, pharmaceutical form and bioequivalence.

III NON-CLINICAL ASPECTS

III.1 Introduction

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

III.2 Pharmacology

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

III.3 Pharmacokinetics

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

III.4 Toxicology

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

III.5 Environmental Risk Assessment

Since these products will be used as substitutes for other products that are currently on the market, no increase in environmental exposure is anticipated. An Environmental Risk Assessment (ERA) is, therefore, not deemed necessary. The applicant has provided suitable information to verify that no increase in the exposure of the environment to the active ingredient is to be expected.

III.6 Discussion on non-clinical aspects

It is recommended that Marketing Authorisations are granted for Lansoprazole 15 mg and 30 mg gastro-resistant capsules, hard.

IV CLINICAL ASPECTS

IV.1 Introduction

No new clinical studies have been performed and none are required for this type of application. A comprehensive review of the published literature has been provided by the applicant.

IV.2 Pharmacokinetics

Peak plasma levels occur within 1.5 to 2 hours following oral administration of lansoprazole. It has high bioavailability (80-90%). The plasma elimination half-life ranges from 1 to 2 hours after single or multiple doses in healthy subjects. Its plasma protein binding is high at 97%. Lansoprazole exhibits a prolonged pharmacological action providing effective acid suppression over 24 hours. Lansoprazole is metabolised substantially by the liver and is excreted by both the renal and biliary route.

Two bioequivalence studies were conducted to compare the bioavailability of Lansoprazole 30mg Gastro-resistant Capsules (Treatment A) versus Zoton 30 mg Gastro-resistant Capsules (Wyeth Laboratories, UK – Treatment B) following administration of a single 30mg capsule in the fasting and fed states.

The clinical parts were carried out in compliance with Good Clinical Practice. These were open-label, single-dose, randomized, two-period, two-sequence, two-treatment, crossover studies designed to evaluate the comparative bioavailability of two formulations of lansoprazole administered to healthy male and female subjects under fasting or fed conditions. Concentrations of lansoprazole were measured from the plasma samples collected over a 12-hour interval after dosing in each period with a washout period of 1 week.

The results of the main pharmacokinetic parameters are summarised below.

Summary of main pharmacokinetic parameters of lansoprazole (single dose, fasting)

Parameter	Geometric Means Arithmetic Means (CV%)		Ratio of Geometric Means (%)	90% Confidence Interval (%)	Intra-Subject (CV%)
	Treatment A	Treatment B			
AUC_{0-t} (ng.h/ml)	2494.77 2928.81 (64)	2465.36 3040.44 (67)	101.19	93.42-109.61	25
AUC_{inf} (ng.h/ml)	2534.94 3044.94 (73)	2507.61 3173.20(77)	101.09	93.38-10943	25
C_{max} (ng/ml)	1044.86 1108.65 (33)	992.29 11115.37(42)	105.30	94.11-117.82	36
T_{max}[a] (h)	1.86(45)	1.75(42)	-	-	-
K_{el}[a] (1h)	0.5697(31)	0.5719(33)	-	-	-
T_{half}[a] (h)	1.42 (55)	1.32(56)	-	-	-
[a]Presented as arithmetic mean (CV%) only.					

Summary of main pharmacokinetic parameters of lansoprazole (single dose, fed)

Parameter	Geometric Means Arithmetic Means (CV%)		Ratio of Geometric Means (%)	90% Confidence Interval (%)	Intra-Subject (CV%)
	Treatment A	Treatment B			
AUC_{0-t} (ng.h/ml)	670.71 961.60 (87)	752.09 1051.71(82)	89.18	74.80 – 106.32	73
AUC_{inf} (ng.h/ml)	719.88 1053.08(92)	779.36 1121.52(92)	92.37	77.85 – 109.59	70
C_{max} (ng/ml)	191.29 269.54(80)	210.58 282.67(74)	90.84	75.00 – 110.04	82
T_{max}[a] (h)	4.60(26)	3.95(37)	-	-	-
K_{el}[a] (1h)	0.4944(40)	0.5241(36)	-	-	-
T_{half}[a] (h)	1.71(58)	1.62(84)	-	-	-
[a]Presented as arithmetic mean (CV%) only.					

Fasting study: The mean relative bioavailability of lansoprazole was 101.09%, with a 90% confidence interval of 93.38-109.43% for the ratio of the ln-transformed AUC_{inf}. The ratio of mean C_{max} ln-transformed values was 105.30% with a 90% confidence interval of 94.11-117.82%. The mean T_{max} values were 1.86 and 1.75 hours for Treatment A and Treatment B, respectively.

The essentially linear pharmacokinetics of lansoprazole, particularly at this relatively low dose range, makes it likely that the lower doses of lansoprazole formulations also are bioequivalent to the corresponding marketed brand formulations, although bioequivalence has not been assessed explicitly.

Fed study: The mean relative bioavailability of lansoprazole was 92.37%, with a 90% confidence interval of 77.85-109.59% for the ratio of the ln-transformed AUC_{inf}. The ratio of mean C_{max} ln-transformed values was 90.84%, with a 90% confidence interval of 75.000-110.04%. The mean T_{max} values were 4.60 and 3.95 hours for Treament A and Treatment B, respectively. The differences between the test and reference products were not found to be statistically significant.

The results of the fasted study indicate bioequivalence. The 90% confidence intervals for the AUC and C_{max} ratios fall within the conventional 80-125% bioequivalence range in the fasting study, but outside this range in the fed one. However, the fed study results comply with the wider 70-143% criterion. It is considered that this wider criterion can be applied in the case of lansoprazole, particularly with its high intra-subject variability (70%-82%) implying a large range of blood drug levels, even when the same product is administered to the same subject on different occasions.

The study under the fed conditions shows a delay in absorption for both reference and test products. The fed study shows both the brand and generic products have their bioavailability reduced, although the generic product is more affected. However, this reduction is not clinically relevant and is consistent with literature data.

The applicant has not provided a biostudy at steady state. An adequate justification has been submitted, supported by relevant documentation, for the exemption of a multiple dose bioequivalence study. Unlike omeprazole, there appears to be no evidence of accumulation with lansoprazole. In addition, lansoprazole exhibits linear pharmacokinetics over the relatively lower dose range (< 60mg) for these applications.

Conclusion
Bioequivalence has been demonstrated between the applicant's Lansoprazole 30mg Gastroresistant Capsules and the originator products Zoton 30 mg Gastro-resistant Capsules (Wyeth Laboratories, UK). As these products meet all the criteria as specified in the Note for Guidance on the investigation of bioavailability and bioequivalence (CPMP/EWP/QWP/1401/98), the results and conclusions of the bioequivalence study on the 30mg strength can be extrapolated to the 15mg strength capsules

IV.3 Pharmacodynamics

Lansoprazole acts by inhibiting, specifically, the hydrogen/potassium ATPase (proton pump) of the parietal cell in the stomach, the terminal step in acid production. This leads to the reduction of gastric acidity, a key requirement for healing of acid-related disorders such as peptic ulceration. A single dose of 30mg inhibits pentagastrin-stimulated acid secretion by approximately 80%, indicating effective acid inhibition from the first day of dosing.

No new data were submitted and none are required for these applications.

IV.4 Clinical Efficacy

No new data on efficacy have been submitted and none are required for an application of this type.

IV.5 Clinical Safety

No serious adverse events were reported during each of the two studies. The majority of adverse events included complaints, such as headache, dizziness, local pain at sites of injection, hot flushes, nausea, vomiting, loose stools, etc.

No additional new data on the safety of lansoprazole were submitted and none are required for this type of application.

IV.7 Discussion of the clinical aspects

It is recommended that Marketing Authorisations are granted for Lansoprazole 15 mg and 30 mg gastro-resistant capsules, hard.

V USER CONSULTATION

The SmPC, PIL and labels are pharmaceutically acceptable. The marketing authorisation holder has stated that the products are not currently being marketed in the UK. However, they have committed to submitting mock-ups for the PIL and labelling (including PIL user testing) before marketing either of the products in the UK.

VI. OVERALL CONCLUSION AND BENEFIT RISK ASSESSMENT AND RECOMMENDATION

The quality of the products is acceptable and no new preclinical or clinical safety concerns have been identified. The bioequivalence study supports the claim that the applicant's products and the innovator products are interchangeable. Extensive clinical experience with lansoprazole is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

PRODUCT LITERATURE

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The texts following the annex are the approved labelling texts for these medicines, no label mock-ups have been provided. In accordance with medicines legislation, the product shall not be marketed in the UK until approval of the label mock-ups has been obtained.

Annex – Table of content of the PAR update for MRP and DCP

Steps taken after the initial procedure with an influence on the Public Assessment Report

(Type II variations, PSURs, commitments)

Scope	Procedure number	Product information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached Y/N (version)
To register a change in composition of the printing inks used for capsule marking, from: shellac, black iron oxide (E172), soya lecithin & antifoaming agent, TO shellac, black iron oxide (E172) & propylene glycol.	UK/H/0884/ 002/IA/001	SmPC and PIL	30/01/2008	05/02/2008	Approved	N
To add HDPE bottles with PP closure and desiccant as an additional package to the product licence- sections 6.5 (Nature and content of container) and 6.4 (Special precautions for storage) of the SPC and labelling are updated.	UK/H/0884/ 001-002/II/008	SmPC and Labelling	09/07/2008	08/12/2008	Approved	N
To update the SmPC and leaflet in line with PRAC recommendations (EMA/PRAC/740369/2016). (The UK national texts have had editorial updates.)	UK/H/0884/ 001-002/IB41	SmPC and PIL	09/10/2017	02/11/2017	Approved	Y

Annex 1

Our Reference:	PL 00289/0675-57, PL 00289/0676-59
Product:	Lansoprazole 15 mg and 30 mg gastro-resistant capsules, hard
Marketing Authorisation Holder:	TEVA UK LIMITED
Active Ingredient(s):	Lansoprazole
Type of Procedure:	Mutual Recognition
Submission Type:	Variation
Submission Category:	Type IB
Submission Complexity:	Standard
EU Procedure Number (if applicable):	UK/H/0884/001-002/IB41

Reason:
To update the SmPC and leaflet in line with PRAC recommendations (EMA/PRAC/740369/2016). (The UK national texts have had editorial updates.)

Supporting Evidence
Document referenced is EMA/PRAC/740369/2016.

Evaluation
Changes are in line with the recommendations.

Conclusion
Updated SmPC and PIL are acceptable.

The updated SmPC and PIL are available on the Medicines and Healthcare products Regulatory Agency website. The approved labelling text can be found below.

Decision: **Approved**
Date: October 2017

PARTICULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Lansoprazole 30 mg gastro-resistant capsules., hard
Lansoprazole

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each capsule, hard contains 15 mg of lansoprazole.

3. LIST OF EXCIPIENTS

Contains sucrose. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

7 gastro-resistant capsules, hard
14 gastro-resistant capsules, hard
15 gastro-resistant capsules, hard
28 gastro-resistant capsules, hard
30 gastro-resistant capsules, hard
50 gastro-resistant capsules, hard
56 gastro-resistant capsules, hard
84 gastro-resistant capsules, hard
98 gastro-resistant capsules, hard
100 gastro-resistant capsules, hard

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Oral use. Take as directed by your doctor.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

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

[Bottle]
Do not store above 25°C.
Store in the original package.
Keep the bottle tightly closed.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
TEVA UK Limited
Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/0676

13. BATCH NUMBER

LOT

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

DOSAGE: Use as directed by the doctor

16. INFORMATION IN BRAILLE

Lansoprazole 30 mg gastro-resistant capsules, hard

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER FOIL

1. NAME OF THE MEDICINAL PRODUCT

Lansoprazole 15 mg gastro-resistant capsules, hard
Lansoprazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

LOT

5. OTHER

N.B: For calendar packs, the foil will also be printed with the days of the week

PARTICULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Lansoprazole 15 mg gastro-resistant capsules, hard

Lansoprazole

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each capsule, hard contains 15 mg of lansoprazole.

3. LIST OF EXCIPIENTS

Contains sucrose. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

7gastro-resistant capsules, hard
14 gastro-resistant capsules, hard
15 gastro-resistant capsules, hard
28 gastro-resistant capsules, hard
30 gastro-resistant capsules, hard
50 gastro-resistant capsules, hard
56 gastro-resistant capsules, hard
84 gastro-resistant capsules, hard
98 gastro-resistant capsules, hard
100 gastro-resistant capsules, hard

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Oral use. Take as directed by your doctor.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

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

[Bottle]
Do not store above 25°C.
Store in the original package.
Keep the bottle tightly closed.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
TEVA UK Limited
Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/0675

13. BATCH NUMBER

LOT

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

DOSAGE: Use as directed by the doctor

16. INFORMATION IN BRAILLE

Lansoprazole 15 mg gastro-resistant capsules, hard

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN: