Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets

(pantoprazole sodium sesquihydrate)

PL 17907/0484-0485

UKPAR

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LAY SUMMARY
Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets
(pantoprazole sodium sesquihydrate)

This is a summary of the Public Assessment Report (PAR) for Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 17907/0484-0485). It explains how Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets.

For practical information about using Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets and what are they used for?
Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets contain the active substance pantoprazole sodium sesquihydrate. Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets are used for treating acid-related diseases of the stomach and intestine.

These medicines are identical to Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 34771/0158 & PL 34771/0005) which were authorised to Macleods Pharma UK Limited on 13th November 2013 and 22nd December 2011, respectively. Macleods Pharma UK Limited has agreed that the scientific data presented for Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 34771/0158 & PL 34771/0005) can be used for the applications for Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 17907/0484-0485).

How are Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets used?
Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets are taken by mouth. These medicines should be taken an hour before a meal and should be swallowed whole (without chewing or breaking them) with some water. The usual dose in adults and adolescents (12 years of age and above) for treating the symptoms of Gastro-oesophageal reflux disease and for the long-term management/prevention of the return of reflux oesophagitis, is one 20 mg tablet a day. The usual dose in adults for the prevention of duodenal and stomach ulcers in patients who need to take non-steroidal anti-inflammatory drugs (NSAID) continuously, is one 20 mg tablet a day.

Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets can only be obtained with a prescription from a doctor.

For further information on how Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets are used, please see the Summary of Product Characteristics or the package leaflet available on the MHRA website.

How do Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets work?
Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets belong to a group of medicines called “proton pump inhibitors”. They work by reducing the amount of acid produced in the stomach.
How have Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets been studied?
Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets are identical to the previously granted applications for Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 34771/0158 & PL 34771/0005; Macleods Pharma UK Limited). The company (Bristol Laboratories Ltd) referred to data provided by Macleods Pharma UK Limited for the grant of licences for Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 34771/0158 & PL 34771/0005) as the basis for the grant of licences for Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 17907/0484-0485).

What are the benefits and risks of Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets?
As Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets are considered identical to Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 34771/0158 & PL 34771/0005), their benefits and risks are taken as being the same as those for Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 34771/0158 & PL 34771/0005).

What are the possible side effects from Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets?
Like all medicines, Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets can cause side effects, although not everybody gets them.

For the full list of all side effects reported with Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets, see section 4 of the package leaflet.

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

Why are Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets approved?
No new or unexpected safety concerns arose from these applications. It was, therefore, considered that the benefits of Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets outweigh the identified risks; and the grant of Marketing Authorisations was recommended.

What measures are being taken to ensure the safe and effective use of Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets?
A risk management plan has been developed to ensure that Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets are used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics and the package leaflet for Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets
Marketing Authorisations were granted in the UK on 18th August 2014.

For more information about taking Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in October 2014.
The full PAR for Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets follows this summary.
Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Bristol Laboratories Ltd Marketing Authorisations for the medicinal products Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 17907/0484-0485) on 18th August 2014.

These prescription-only medicines (POM) are indicated in adults and adolescents 12 years of age and above for symptomatic treatment of gastro-oesophageal reflux disease, and for long-term management and prevention of relapse in reflux oesophagitis. In adults it is also indicated for prevention of gastroduodenal ulcers induced by non-selective non-steroidal anti-inflammatory drugs (NSAID), in patients that are at risk and need continuous NSAID treatment.

These applications were submitted as simple applications according to Article 10c of Directive 2001/83/EC, as amended. The applicant has cross-referred to Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 34771/0158 & PL 34771/0005), which were authorised to Macleods Pharma UK Limited on 13th November 2013 and 22nd December 2011, respectively.

No new data were submitted nor were they necessary for these simple applications, as the data are identical to those of the previously granted cross-reference products.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these product types at all sites responsible for the manufacture and assembly of these products.

A summary of the pharmacovigilance system and a detailed risk management plan have been provided with these applications and these are satisfactory.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 17907/0484-0485

PROPRIETARY NAME: Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets

COMPANY NAME: Bristol Laboratories Ltd

E.C. ARTICLE: Article 10c of Directive 2001/83/EC, as amended

LEGAL STATUS: POM

1 INTRODUCTION

These are informed consent applications for Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets, submitted under Article 10c of Directive 2001/83/EC, as amended. The applicant has cross-referred to Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 34771/0158 & PL 34771/0005), which were originally authorised to Macleods Pharma UK Limited on 13th November 2013 and 22nd December 2011, respectively.

The current applications are considered valid.

2 MARKETING AUTHORISATION APPLICATIONS (MAAs)

2.1 Name(s)

The proposed names of the products are Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets. These products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

These products are tablets for oral use and contain 20 mg and 40 mg pantoprazole (as sodium sesquihydrate).

The tablets are packed in orientated polyamide (OPA)/aluminium/polyvinylchloride (PVC)/aluminium blisters containing 28 Tablets.

Specifications and Certificates of Analysis for all packaging components used have been provided and are satisfactory. The packaging and pack size are the same as those for the cross-reference products.

The proposed shelf-lives are 3 years (20 mg formulation) and 24 months (40 mg formulation) with a storage condition “Do not store above 25°C”. These are acceptable.

2.3 Legal status

Pantoprazole 20 mg Gastro-resistant Tablets are prescription-only medicines (POM).

2.4 Marketing Authorisation Holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Bristol Laboratories Ltd, Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire, HP4 1EG, United Kingdom
2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference products and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed formulae are consistent with the details registered for the cross-reference products.

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

2.8 Finished product specifications
The proposed finished product specifications, at release and shelf-life, are in line with the details registered for the cross-reference products.

2.9 Drug substance specifications
The proposed drug substance specifications conform to the current European Pharmacopoeia monograph for pantoprazole sodium sesquihydrate and are in-line with those for the cross-reference products.

A European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability for the manufacture of pantoprazole sodium sesquihydrate has been provided. The active substance manufacturer is the same as the manufacturer approved for the cross-reference products.

2.10 TSE Compliance
No materials of animal or human origin are included in these products. This is consistent with the cross-reference products.

2.11 Bioequivalence
No bioequivalence data are required to support these informed consent applications, as the proposed products are manufactured to the same formula utilising the same process as the cross-reference products Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 34771/0158 & PL 34771/0005).

3 EXPERT REPORTS
The applicant has cross-referred to the data for cross-reference products, Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 34771/0158 & PL 34771/0005), to which they are claimed to be identical. This is acceptable. The applicant has included detailed expert reports for the applications. Signed declarations and copies of the experts’ CVs are enclosed 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 names. The appearance of the products is identical to those of the cross-reference products.
5. **SUMMARIES OF PRODUCT CHARACTERISTICS (SmPCs)**
The proposed SmPCs are consistent with the details registered for the cross-reference products.

6. **PATIENT INFORMATION LEAFLET (PIL)/LABELLING**
User testing of the package leaflet has been accepted, based on bridging reports provided by the applicant making reference to the user-testing of the PIL for Pantoprazole 40 mg Gastro-resistant Tablets (PL 34771/0005). The products are from the same therapeutic class and have similar indications. A critical analysis demonstrated that the key messages for safe and effective use for both leaflets were similar. The justification on the rationale for bridging is accepted.

The proposed artwork complies with the relevant statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and sufficient space for a standard UK pharmacy dispensing label.

7. **CONCLUSION**
The data submitted with the applications are acceptable. The grant of Marketing Authorisations is recommended.
NON-CLINICAL ASSESSMENT

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

A suitable justification has been provided for not submitting an environmental risk assessment.
CLINICAL ASSESSMENT

No new clinical data have been supplied with these applications and none are required for applications of this type.
OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
The data for these applications are consistent with those previously assessed for the cross-reference products and, as such, have been judged to be satisfactory.

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

CLINICAL
These applications are identical to the previously granted applications for Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets (PL 34771/0158 & PL 34771/0005), authorised to Macleods Pharma UK Limited on 13th November 2013 and 22nd December 2011, respectively.

No new or unexpected safety concerns arose from these applications.

The SmPCs, PILs and labelling are satisfactory and consistent with those for the cross-reference products.

BENEFIT RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical concerns have been identified. The applicant’s products are identical to the cross-reference products. Extensive clinical experience with pantoprazole sodium sesquihydrate is considered to have demonstrated the therapeutic value of the compound. The benefit risk is, therefore, considered to be positive.
Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets

PL 17907/0484-0485

STEPS TAKEN FOR ASSESSMENT

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<td>The MHRA received the Marketing Authorisation applications on 7th March 2014</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPCs) for products that have been granted Marketing Authorisations at a national level are available on the MHRA website.
PATIENT INFORMATION LEAFLET

In accordance with Directive 2010/84/EU the Patient Information Leaflets (PILs) for products that have been granted Marketing Authorisations at a national level are available on the MHRA website.
LABELLING
UKPAR Pantoprazole 20 mg and 40 mg Gastro-resistant Tablets

PL 17907/0484-0485

Pantoprazole 40 mg gastro-resistant tablets

Each gastro-resistant tablet contains Pantoprazole 40 mg (as the sodium sesquihydrate)

Affix Dispensing Label Here

For oral use only. Swallow whole. Do not break, chew or crush tablets.

Do not store above 25°C. Keep out of the reach and sight of children. Please read the enclosed leaflet before using this product.