

Omeprazole 20 mg gastro-resistant tablets

PL 14017/0277

UKPAR

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OMEPRAZOLE 20 MG GASTRO-RESISTANT TABLETS

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LAY SUMMARY

This is a summary of the public assessment report (PAR) for Omeprazole 20 mg gastro-resistant tablets. It explains how Omeprazole 20 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 Omeprazole 20 mg gastro-resistant tablets.

For practical information about using Omeprazole 20 mg gastro-resistant tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Omeprazole 20 mg gastro-resistant tablets and what are they used for?

Omeprazole 20 mg gastro-resistant tablets belong to a group of medicines called the ‘proton pump inhibitors’. They work by reducing the amount of acid that the stomach produces.

Omeprazole 20 mg gastro-resistant tablets are used in adults for the short-term treatment of reflux symptoms (for example, heartburn, acid regurgitation). Reflux is the backflow of acid from the stomach into the gullet “foodpipe”, which may become inflamed and painful. This may cause symptoms such as a painful burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation).

How do Omeprazole 20 mg gastro-resistant tablets work?

Omeprazole works by reducing the amount of acid that the stomach produces. The tablets release the active ingredient in the intestine, where it is absorbed by the body to give an effect.

How are Omeprazole 20 mg gastro-resistant tablets used?

Omeprazole 20 mg gastro-resistant tablets should be swallowed whole with half a glass of water.

The recommended dose is one 20 mg tablet once a day for 14 days. A doctor should be contacted if the patient is not free from symptoms after this period. It might be necessary to take the tablets for 2-3 consecutive days to achieve improvement of symptoms.

It is recommended that the tablets are taken in the morning and they can be taken with food or on an empty stomach. Tablets should not be chewed or crushed as this would break the special coating which stops the medicine from being broken down by acid in the stomach. This medicine can be obtained from a pharmacy without a prescription.

What benefits of Omeprazole 20 mg gastro-resistant tablets have been shown in studies?

Omeprazole 20 mg gastro-resistant tablets are considered to be identical to the Omeprazole 20 mg Gastro-resistant Tablets, previously authorised to Dexcel Pharma Limited, with the same benefits and risks. Therefore, no new studies have been provided for Omeprazole 20 mg gastro-resistant tablets but reference is made to the Marketing Authorisation for the reference product.

What are the possible side effects from Omeprazole 20 mg gastro-resistant tablets?

The most common side effects with Omeprazole 20 mg gastro-resistant tablets, which affect up to 1 in 10 people, are headache, effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence) and feeling sick (nausea) or being sick (vomiting).

For the full list of all side effects reported with Omeprazole 20 mg gastro-resistant tablets, see section 4 of the package leaflet. For the full list of restrictions, see the package leaflet.

Why are Omeprazole 20 mg gastro-resistant tablets approved?

The MHRA decided that the benefits of Omeprazole 20 mg gastro-resistant tablets are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Omeprazole 20 mg gastro-resistant tablets?

Safety information has been included in the Summary of Product Characteristics and the package leaflet for Omeprazole 20 mg gastro-resistant tablets, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

Other information about Omeprazole 20 mg gastro-resistant tablets

A Marketing Authorisation was granted in the UK on 17 May 2007.

This summary was last updated in April 2015.

The full PAR for Omeprazole 20 mg gastro-resistant tablets follows this summary.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Dexcel Pharma Limited a Marketing Authorisation for the medicinal product Omeprazole 20 mg gastro-resistant tablets on 17 May 2007.

This medicine is used to treat reflux symptoms (*e.g.* heartburn, acid regurgitation) in adults. It is available from a pharmacy without a prescription.

This application was submitted as an abridged application, according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to the Marketing Authorisation for Omeprazole 20 mg Gastro-resistant Tablets (PL 14017/0042) which was granted to Dexcel Pharma Limited on 19 March 2002.

Omeprazole, a racemic mixture of two enantiomers reduces gastric acid secretion through a highly targeted mechanism of action. It is a specific inhibitor of the acid pump in the parietal cell. It is rapidly acting and provides control through reversible inhibition of gastric acid secretion with once daily dosing.

Omeprazole is a weak base and is concentrated and converted to the active form in the highly acidic environment of the intracellular canaliculi within the parietal cell, where it inhibits the enzyme $H^+ K^+$ -ATPase - the acid pump. This effect on the final step of the gastric acid formation process is dose-dependent and provides for highly effective inhibition of both basal acid secretion and stimulated acid secretion, irrespective of stimulus.

No new data were submitted nor were necessary for this simple application, as the data are identical to those provided for the previously authorised product.

This application is a duplicate of a previously granted application for Omeprazole 20 mg Gastro-resistant Tablets (PL 14017/0042; Dexcel Pharma Limited) and, as such, these products can be used interchangeably.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Omeprazole 20mg gastro-resistant tablets outweigh the risks, hence a Marketing Authorisation has been granted.

PHARMACEUTICAL ASSESSMENT

LICENCE NO:	PL 14017/0277
PROPRIETARY NAME:	Omeprazole 20 mg gastro-resistant tablets
ACTIVE:	Omeprazole
COMPANY NAME:	Dexcel Pharma Limited
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS:	P

1. INTRODUCTION

This is an abridged application for Omeprazole 20 mg gastro-resistant tablets (PL 14017/0277), submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Omeprazole 20 mg Gastro-resistant Tablets (PL 14017/0042 Dexcel Pharma Limited). The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name

The name of the product is acceptable.

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

The product has the same strength, form and route of administration as the reference product.

Omeprazole 20 mg gastro-resistant tablets are stored in aluminum blister packs. Pack sizes of 7 and 14 tablets have been authorised, although not all pack sizes may be marketed.

2.3 Legal status

Omeprazole 20 mg gastro-resistant tablets are available from pharmacies without a prescription.

2.4 Marketing Authorisation Holder

The Marketing Authorisation Holder is Dexcel Pharma Limited, 7 Sopwith Way, Drayton Fields Industrial Estate, Daventry, Northamptonshire NN11 8P8, United Kingdom.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

2.5 Manufacturers

The manufacturing sites are identical to those of the reference product and are acceptable.

2.6 Qualitative and quantitative composition

The product's composition is identical to that of the reference product and is acceptable.

2.7 Manufacturing process

The manufacturing process is identical to that of the reference product and is acceptable.

2.8 Finished product/shelf-life specification

The finished product specification is identical to that of the reference product and is acceptable.

2.9 Drug substance specification

The drug substance specification is identical to that of the reference product and is acceptable.

2.10 TSE Compliance

No ingredients of human or animal origin are used to make the medicinal product.

2.11 Bioequivalence

No bioequivalence data are required to support this simple abridged application because the product is identical to a product that is already authorised.

3. EXPERT REPORTS

These are acceptable.

4. PRODUCT NAME AND APPEARANCE

The name of and appearance of the product are essentially identical to those of the reference product and are acceptable.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The Summary of Product Characteristics is identical to that of the reference product, apart from the necessary administrative updates to reflect the change in Marketing Authorisation, and is acceptable.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING

The PIL and labels are identical to those of the reference product, apart from the necessary administrative updates to reflect the change in Marketing Authorisation, and are acceptable.

7. CONCLUSION

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

NON-CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA).

The grant of a Marketing Authorisation is recommended.

CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

The Risk Management Plan is considered adequate. Routine risk minimisation is provided through the Summary of Product Characteristics and the Patient Information Leaflet and this is sufficient.

The grant of a Marketing Authorisation is recommended.

OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY

The data for this application are consistent with the data previously assessed for the Marketing Authorisation for Omeprazole 20 mg Gastro-resistant Tablets (PL 14017/0042; Dexcel Pharma Limited) and, as such, have been judged to be satisfactory.

NON-CLINICAL

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

EFFICACY

The product is identical to that previously licensed for Omeprazole 20 mg Gastro-resistant Tablets (PL 14017/0042; Dexcel Pharma Limited); therefore, no efficacy data are needed.

SAFETY

No new or unexpected safety concerns arose from this application.

PRODUCT LITERATURE

The SmPC, PIL and labels are identical to those previously approved, apart from the necessary administrative updates to reflect the change in Marketing Authorisation.

BENEFIT/RISK ASSESSMENT

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to Omeprazole 20 mg Gastro-resistant Tablets (PL 14017/0042; Dexcel Pharma Limited). The benefit/risk balance is therefore considered to be positive.

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STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the Marketing Authorisation application on 20 January 2005.
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 27 April 2005.
- 3 Following assessment of the application the MHRA requested further information relating to the dossier on 11 November 2005.
- 4 The applicant responded to the MHRA's requests, providing further information on 15 February 2006 and 30 January 2007.
- 5 The Marketing Authorisation was granted on 17 May 2007.

STEPS TAKEN AFTER INITIAL AUTHORISATION – SUMMARY

Date submitted	Application type	Scope	Outcome
10/11/2011	Type IA variation	1. To change the address of the Marketing Authorisation Holder (MAH), Dexcel Pharma Ltd. 2. To change the address of the manufacturer responsible for batch release, Dexcel Pharma Ltd.	29/12/2011 - granted
30/11/2011	Type IB variation	To update module M.1.8.1 with the introduction of a new pharmacovigilance system.	03/01/2012 - granted
03/01/2012	Type IB variation	To update sections 2 (Qualitative and quantitative composition), 3 (Pharmaceutical form), 4 (Clinical particulars), 5 (Pharmacological properties), 6.1 (List of excipients), 6.4 (Special precautions for storage), 6.5 (Nature and content of container) and 6.6 (Special precautions for disposal) of the SmPC, and the label and leaflet in line with the brand leader.	17/05/2012 - granted
30/05/2012	Type IB variation	To update sections 4.4 (Special Warnings) and 4.8 (Undesirable Effects) of the SmPC in line with PhVWP (CMDh/PhVWP/047/2012) & (CMDh/PhVWP/048/2012) to include information concerning proton pump inhibitors and the risk of fractures to the hip, wrist and spine as well as severe hypomagnesaemia. Consequently the leaflet has been updated.	02/08/2012 - granted
30/01/2013	Type IA variation	To register the replacement of Detailed Description of the Pharmacovigilance System (DDPS) Version 4 with Pharmacovigilance System Master File (PSMF).	19/02/2013 - granted

29/05/2013	Type IB variation	To update sections 4.5 (Interaction with other medicinal products and other forms of interaction) and 4.8 (Undesirable effects) of the SmPC and consequentially the leaflet in line with the brand leader.	17/06/2013 - granted
24/11/2008	Type II variation	To reclassify the status of the medicinal product from Prescription Only Medicine (POM) to Pharmacy (P).	20/12/2013 - granted
12/05/2014	Change of Ownership	Change of Marketing Authorisation Holder from Dexcel [®] -Pharma Ltd (PL 14017/0136) to Dexcel [®] Pharma Laboratories Ltd (PL 31623/0099)	12/05/2014 - granted
08/01/2015	Change of Ownership	Change of Marketing Authorisation Holder from Dexcel [®] Pharma Laboratories Ltd (PL 31623/0099) to Dexcel Pharma Limited (PL 14017/0277)	08/01/2015 - granted
16/02/2015	Type IB variation	To update the SmPC, sections 4.2, 4.3, 4.4, 4.6, 4.8 and 5.2 in line with the reference product, Losec. As a consequence, the PIL has been updated.	23/03/2015 - granted

SUMMARY OF PRODUCT CHARACTERISTICS

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

LABELLING

Blister:

Omeprazole 20mg Gastro-Resistant Tablets Dexcel®-Pharma Ltd.	Omeprazole 20mg Gastro-Resistant Tablets Dexcel®-Pharma Ltd.
Omeprazole 20mg Gastro-Resistant Tablets Dexcel®-Pharma Ltd.	Omeprazole 20mg Gastro-Resistant Tablets Dexcel®-Pharma Ltd.
Omeprazole 20mg Gastro-Resistant Tablets Dexcel®-Pharma Ltd.	Omeprazole 20mg Gastro-Resistant Tablets Dexcel®-Pharma Ltd.
Omeprazole 20mg Gastro-Resistant Tablets Dexcel®-Pharma Ltd.	Omeprazole 20mg Gastro-Resistant Tablets Dexcel®-Pharma Ltd.
Omeprazole 20mg Gastro-Resistant Tablets Dexcel®-Pharma Ltd.	Omeprazole 20mg Gastro-Resistant Tablets Dexcel®-Pharma Ltd.

Carton:



<p>Omeprazole 20mg Gastro-Resistant Tablets PL 14017/0277</p>	<p>20 mg 14 Gastro-Resistant Tablets</p>	<p>V-1138</p>
<p>24 HOUR Long Lasting Relief</p> <ul style="list-style-type: none"> Convenient once a day treatment Effectively relieves Heartburn and Acid Reflux <p>Omeprazole 20mg Gastro-Resistant Tablets</p> <p>14 Gastro-Resistant Tablets</p> <p>Dexcel® pharma</p>		<p>B.N. Man. Exp.</p>
<p>MARKETING AUTHORISATION HOLDER: P DEXCEL® - PHARMA LTD., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK</p>	<p>20 mg 14 Gastro-Resistant Tablets</p>	<p>D-209</p>
<p>20 mg Omeprazole 20mg Gastro-Resistant Tablets 14 Gastro-Resistant Tablets</p>	<div style="text-align: center;">  </div> <p>Information for user: Read the package leaflet before use. Uses: For short-term treatment of reflux symptoms (for example, heartburn, acid regurgitation) in adults. Take one 20 mg tablet once a day for 14 days. Contact your doctor if you are not free from symptoms after this period. The tablets should be swallowed whole and should not be chewed or crushed. For oral use.</p> <p>Warning: Keep out of the sight and reach of children. Do not exceed the stated dose.</p> <p>Ingredients: Each gastro-resistant tablet contains 20mg omeprazole. Also contains lactose. See leaflet for further information.</p> <p>Storage conditions: Do not store above 30°C. Store in the original package in order to protect from moisture.</p>	<p>Dexcel® pharma</p>