Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

Mutual Recognition Procedure

Perindopril 2, 4 and 8 mg Tablets

(perindopril tert-butylamine)

Procdure: numbers: UK/H/1065/001-3/MR

UK Licence No: PL 00530/0764-6

Norton Healthcare Limited

LAY SUMMARY
Perindopril 2, 4 and 8 mg Tablets
(perindopril tert-butylamine)

This is a summary of the Public Assessment Report (PAR) for Perindopril 2, 4 and 8 mg Tablets (PL 00530/0764-6; UK/H/1065/001-3/MR). For ease of reading, these medicinal products will be referred to as Perindopril Tablets in this Lay Summary.

This summary explains how Perindopril Tablets were assessed and their authorisations recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

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

What are Perindopril Tablets and what are they used for?
Perindopril Tablets are 'generic medicines'. This means that Perindopril Tablets are similar to 'reference medicines' already authorised in the UK called Coversyl 2, 4 and 8 mgTablets (Les Laboratoires Servier; PL 05815/0001-2 & PL 05815/0023).

Perindopril tablets are used:
- In the treatment of high blood pressure (hypertension)
- To treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs)
- to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.

How are Perindopril Tablets used?
Perindopril Tablets are taken orally. The whole tablet should be swallowed with a drink of water, preferably at the same time each day (in the morning), before a meal. If a patient is taking water tablets (diuretics), a doctor may decide to reduce or even discontinue these at the beginning of the treatment with Perindopril Tablets.

Perindopril tablets may be used on its own or with other medicines which lower blood pressure. The recommended dosages are as follows:

- High blood pressure: the usual starting and maintenance dose for treatment in adults is 4 mg once a day. After a month, this can be increased to 8 mg a day which is the maximum recommended dose. In the elderly, the usual starting dose is 2 mg once a day. After a month, this can be increased to 4 mg a day and if necessary to 8 mg a day.
- Heart failure: treatment should be started under close medical supervision with 2 mg once a day. After two weeks, it can be increased to 4 mg once a day if required.
- Stable coronary artery disease: the usual starting dose is 4 mg once daily. After 2 weeks and if 4 mg is well tolerated, this can be increased to 8 mg once daily.

If a patient is 65 or over, the usual starting dose is 2 mg once daily. After one week, this can be increased to 4 mg once daily and after a further week to 8 mg once a day.

A blood test may be done by a doctor to check that the kidneys are working properly before increasing the dose to 8 mg.

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

Perindopril Tablets can only be obtained on prescription from a doctor.

How do Perindopril Tablets work?
Perindopril Tablets contain the active ingredient perindopril tert-butylamine, which belongs to a class of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. These work by widening the blood vessels, which makes it easier for the heart to pump blood through them.

How have Perindopril Tablets been studied?
Because Perindopril Tablets are generic medicines, studies in patients have been limited to tests to determine that they are bioequivalent to the reference products, Coversyl 2, 4 and 8 mg Tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Perindopril Tablets?
As Perindopril Tablets are generic medicines that are bioequivalent to the reference products, Coversyl 2, 4 and 8 mg Tablets, their benefits and risks are taken as being the same as the reference products.

Why are Perindopril Tablets approved?
It was concluded that, in accordance with EU requirements, Perindopril Tablets have been shown to have comparable quality and are bioequivalent to Coversyl 2, 4 and 8 mg Tablets. Therefore, the view was that, as for Coversyl 2, 4 and 8 mg Tablet the benefits outweigh the identified risks.

What measures are being taken to ensure the safe and effective use of Perindopril Tablets?
Safety information has been included in the summaries of Product Characteristics (SmPCs) and the package leaflet for Perindopril Tablets including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Perindopril Tablets
National Marketing Authorisations were granted in the UK on 11 December 2006.

Mutual Recognition Procedures were completed on 07 November 2007, involving the following Concerned Member States (CMSs):

- PL 00530/0764; UK/H/1065/001/MR - Denmark, Germany, Hungary, Luxembourg, Slovenia
- PL 00530/0765; UK/H/1065/002/MR - Bulgaria, Denmark, Germany, Greece, Hungary, Italy, Luxembourg, Republic of Ireland, Romania, Slovenia, Slovakia, Spain
- PL 00530/0766; UK/H/1065/003/MR - Bulgaria, Denmark, Germany, Greece, Hungary, Luxembourg, Republic of Ireland, Romania, Slovakia, Spain

The full PAR for Perindopril Tablets follows this summary.

This summary was last updated in May 2018.

TABLE OF CONTENTS

I	Introduction	Page 5
II	Quality aspects	Page 6
III	Non-clinical aspects	Page 8
IV	Clinical aspects	Page 8
V	User consultation	Page 9
VI	Overall conclusion, benefit/risk assessment and recommendation	Page 10
	Table of content of the PAR update for MRP and DCP	Page 17
	Annex	Page 18

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the member states considered that the applications for Perindopril 2, 4 and 8 mg Tablets are approvable. These are prescription only medicines (POM), and are indicated for the treatment of:

- Hypertension

- Symptomatic Heart Failure

- Stable coronary artery disease:
  Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation

These applications were submitted as abridged applications, according to Article 10(1) of Directive 2001/83/EC, as amended, claiming to be generic medicinal products. The applicant has cross-referred to Coversyl 2, 4 and 8 mg Tablets, which were originally authorised to Les Laboratoires Servier (PL 05815/0001-2 & PL 05815/0023) on 15 December 1989 and 12 June 2002, respectively.

Perindopril is an inhibitor of the enzyme that converts angiotensin I into angiotensin II (Angiotensin Converting Enzyme (ACE) inhibitors). The converting enzyme, or kinase, is an exopeptidase that allows conversion of angiotensin I into the vasoconstrictor angiotensin II as well as causing the degradation of the vasodilator bradykinin into an inactive heptapeptide. Inhibition of ACE results in a reduction of angiotensin II in the plasma, which leads to increased plasma renin activity (by inhibition of the negative feedback of renin release) and reduced secretion of aldosterone. Since ACE inactivates bradykinin, inhibition of ACE also results in an increased activity of circulating and local kallikrein-kinin systems (and thus also activation of the prostaglandin system). It is possible that this mechanism contributes to the blood pressure-lowering action of ACE inhibitors and is partially responsible for certain of their side effects (e.g. cough).

Perindopril acts through its active metabolite, perindoprilat. The other metabolites show no inhibition of ACE activity *in vitro*.

A bioequivalence study was submitted to support these applications comparing the applicant's test product Perindopril 8 mg Tablets and Coversyl 8 mg Tablets (Les Laboratoires Servier) in normal healthy subjects under fasting conditions. The applicant has stated that the bioequivalence studies were carried out in accordance with Good Clinical Practice (GCP).

With the exception of the bioequivalence study, no new clinical data were submitted, which is acceptable given that these applications were based on the products being generic medicinal products of originator products that have been in clinical use for over 10 years.

National Marketing Authorisations were granted in the UK on 11 December 2006.

Mutual Recognition Procedures were completed on 07 November 2007, involving the following Concerned Member States (CMSs):

- PL 00530/0764; UK/H/1065/001/MR - Denmark, Germany, Hungary, Luxembourg, Slovenia
- PL 00530/0765; UK/H/1065/002/MR - Bulgaria, Denmark, Germany, Greece, Hungary, Italy, Luxembourg, Republic of Ireland, Romania, Slovenia, Slovakia, Spain
- PL 00530/0766; UK/H/1065/003/MR - Bulgaria, Denmark, Germany, Greece, Hungary, Luxembourg, Republic of Ireland, Romania, Slovakia, Spain.

II QUALITY ASPECTS

II.1 Introduction

The finished product is formulated as a tablet containing 2 mg, 4 mg and 8 mg perindopril tert-butylamine equivalent to 1.669 mg, 3.338 mg and 6.676 mg of perindopril, as the active ingredient.

Other ingredients consist of the following pharmaceutical excipients: cellulose, microcrystalline (E460), lactose anhydrous, silica colloidal anhydrous, magnesium stearate (E572) and maize starch.

All excipients comply with their respective European Pharmacopoeia monographs. Satisfactory Certificates of Analysis have been provided for all excipients showing compliance with their proposed specifications.

None of the excipients used contain material of animal or human origin with the exception lactose anhydrous. The supplier of lactose has provided a general statement regarding their compliance with EMEA/410/01 Rev. 02. BSE/TSE statements have been provided from the suppliers of the other excipients indicating that they are not manufactured from materials of animal origin. Confirmation has also been given that the magnesium stearate used in the tablets is of vegetable origin.

This product does not contain or consist of genetically modified organisms (GMO).

The finished products are packed in clear, colourless polyvinylchloride (PVC)/Vinyl Acetate - Maleic Acid - Vinyl Chloride Copolymer (VMCH) coated aluminium foil. The blisters are then packed in aluminium pouches containing a silica gel canister (desiccant). The sealed pouches are further packed in cartons.

Perindopril Tablets are also packed in push-through aluminium–aluminium blisters.

The pack sizes are 14, 15, 30, 60, 90 and 120 tablets. Not all pack sizes may be marketed.

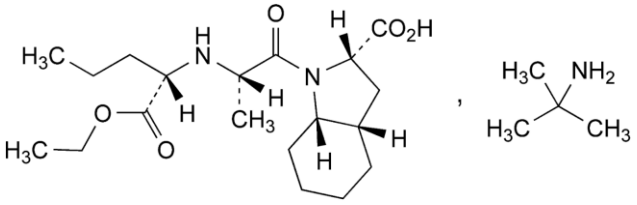
Specifications and Certificates of Analysis for all packaging materials have been provided. These are satisfactory. All primary product packaging complies with EU legislation, Directive 2002/72/EC (as amended), and is suitable for contact with foodstuffs.

II.2. Drug Substance

INN: Perindopril tert-butylamine

Chemical name: 2-Methylpropan-2-amine (2*S*,3a*S*,7a*S*)-1-[(2*S*)-2-[[(1*S*)-1-(ethoxycarbonyl)butyl]amino]propanoyl]octahydro-1*H*-indole-2-carboxylate.

Structure:



Molecular formula: $C_{23}H_{43}N_3O_5$

Molecular weight: 441.6 g/mol

Description: White or almost white, slightly hygroscopic, crystalline powder.

Solubility: Freely soluble in water and in ethanol (96 per cent), soluble or sparingly soluble in methylene chloride.

Perindopril tert-butylamine is the subject of an active substance master file (ASMF).

Synthesis of the active 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.

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. Satisfactory Certificates of Analysis have been provided for all working standards. Batch analysis data that comply with the proposed specification are provided.

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 supporting a suitable retest period when stored in the proposed packaging.

II.3. Medicinal Product

Pharmaceutical Development

The objective of the development programme was to formulate safe, efficacious, stable tablets containing 2, 4 and 8 mg perindopril tert-butylamine per tablet that are generic versions of the reference products Coversyl 2, 4 and 8 tablets (Les Laboratoires Servier). A satisfactory account of the pharmaceutical development has been provided.

Details of the batches used for stability and bioequivalence have been provided. Comparative *in vitro* dissolution and impurity profiles have been provided and have demonstrated the similarity of the test and innovator products. The *in vivo* bioequivalence study was performed using Perindopril 8 mg Tablets and Coversyl 8 mg Tablets.

Manufacture of the products

Appropriate details of the manufacturing process development have been provided. Process validation has been carried out on a pilot scale and commercial scale batches. The protocols and reports are presented and provide a detailed investigation of the process. The manufacturing process appears robust and will consistently produce a product of acceptable quality. The applicant has also confirmed that process validation studies will also be undertaken on the first commercial scale batches manufactured.

Finished Product Specifications

The finished product specifications proposed are acceptable. The test methods have been described and have been adequately validated. Batch data that comply with the release specifications have been provided. Certificates of Analysis have been provided for all working standards used.

Stability of the Product

Finished product stability studies were performed on batches of finished products in the packaging proposed for marketing in accordance with current guidelines. The data from these studies support a shelf-life of 36 months for PVC/VMCH and 24 months for blisters. Once the foil pouch is open the produt must be used within 30 days of opening. The recommended storage conditions are “Keep the blister in the foil pouch in the outer carton in order to protect from moisture” and “Do not store above 25°C”. These are satisfactory.

II.4 Discussion on chemical, pharmaceutical and biological aspects

There are no objections to the approval of these products from a pharmaceutical perspective.

III NON-CLINICAL ASPECTS

III.1 Introduction

The pharmacodynamic, pharmacokinetic and toxicological properties of perindopril tert-butylamine are well-known. No new non-clinical data have been submitted for these applications and none are required.

The applicant has provided an overview based on published literature. The non-clinical overview has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the products' pharmacology and toxicology.

III.2 Pharmacology

No new pharmacology data are required for these applications and none have been submitted.

III.3 Pharmacokinetics

No new pharmacokinetic data are required for these applications and none have been submitted.

III.4 Toxicology

No new toxicology data are required for these applications and none have been submitted.

III.5 Ecotoxicity/environmental risk assessment (ERA)

As these products are intended for generic substitution with other products already on the market, no increase in environmental exposure is anticipated. An ERA is, therefore, not deemed necessary.

III.6 Discussion on the non-clinical aspects

There are no objections to the approval of these products from a non-clinical perspective.

IV CLINICAL ASPECTS

IV.1 Introduction

The clinical pharmacology of perindopril tert-butylamine is well-known. With the exception of the bioequivalence study detailed below, no new clinical studies have been performed and none are required for this type of applications. The applicant's clinical overview has been written by an appropriately qualified person and is considered acceptable.

IV.2 Pharmacokinetics

In support of these applications, the Marketing Authorisation Holder has submitted an open label, single-dose, randomised, two-period, cross-over comparative bioavailability study of the test product Perindopril 8 mg Tablets and Coversyl® 8 mg Tablets (Les Laboratoires Servier) in healthy, adult, human subjects under fasting conditions.

Blood samples were collected for plasma levels before dosing and up to and including 24 hours after each administration. The washout period between the treatment phases was 31 – 35 days.

Summary statistics for the pharmacokinetic parameters for plasma levels of perindopril and perindoprilat are provided below:

Parameters (Perindopril)	**Perindopril 8 mg (test)**	**Coversyl 8 mg (reference)**	**Point estimate (%)(test/reference)**	**90 % C.I. (test/reference)**
C_{max} (ng/ml)	166	158	105	97.2 – 114
$AUC_{(0-t)}$ (ngh/ml)	251	256	98.1	94.9 – 102
$AUC_{(0-inf)}$ (ngh/ml)	252	257	98.2	94.9 – 102
T_{max} (h)	0.75	0.75	-	-
$T_{1/2}$ (h)	1.08	1.07	-	-

Parameters (Perindorpilat)	**Perindopril 8 mg (test)**	**Coversyl 8 mg (reference)**	**Point estimate (%)(test/reference)**	**90 % C.I. (test/reference)**
C_{max} (ng/ml)	29.9	29.8	100	96.1 – 104
$AUC_{(0-t)}$ (ngh/ml)	283	277	102	99.4 – 105
$AUC_{(0-inf)}$ (ngh/ml)	328	320	103	99.9 – 105
T_{max} (h)	1.67	1.67	-	-
$T_{1/2}$ (h)	35.9	35.4	-	-

Conclusion
The 90% confidence intervals of the test/reference ratio for AUC_{0-t}, $AUC_{(0-inf)}$ and C_{max} values for both analytes lie within the acceptable limits of 80.00% to 125.00%, in line with the 'Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1/Corr**). Thus, the data support the claim that the applicant's test product (Perindopril 8 mg Tablets) is bioequivalent to the reference product Coversyl® 8 mg Tablets (Les Laboratoires Servier).

As the 2, 4 and 8 mg strength test products meet the biowaiver criteria specified in the current bioequivalence guidance, the results and conclusions of the bioequivalence study with the 8 mg tablet strength can be extrapolated to the 2 mg and 4 mg strength tablets.

IV.3 Pharmacodynamics
No new pharmacodynamic data were submitted and none were required for these applications.

IV.4 Clinical efficacy
No new efficacy data were submitted, and none were required for these applications.

IV.5 Clinical safety
No new safety data were submitted, and none were required for these applications.

IV.6 Pharmacovigilance System
Safety information has been included in the summaries of Product Characteristics (SmPCs) and the Patient Information Leaflet (PIL), including the appropriate precautions to be followed by healthcare professionals and patients.

Discussion on the clinical aspects
The grant of Marketing Authorisations is recommended for these applications.

V User consultation
The package leaflet has been evaluated via a user consultation study, in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC, as amended. The language used for the purpose of user testing the PIL was English.

The results show that the package leaflet meets the criteria for readability, as set out in the *guideline on the readability of the label and package leaflet of medicinal products for human use*.

VI Overall conclusion, benefit/risk assessment and recommendation

The quality of the products is acceptable, and no new non-clinical or clinical concerns have been identified. The applicant's product is identical to the reference product. Extensive clinical experience with perindopril tert-butylamine is considered to have demonstrated the therapeutic value of the compound. The benefit-risk assessment is, therefore, considered to be positive.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels
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 approved labelling for Perindopril 2 mg, 4mg and 8 mg Tablets is presented below:

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Perindopril 2 mg Tablets
Perindopril tert-butylamine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains perindopril tert-butylamine 2 mg equivalent to 1.669 mg perindopril.

3. LIST OF EXCIPIENTS

Contains lactose, see leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

14 Tablets
15 tablets
30 Tablets
60 Tablets
90 Tablets
120 Tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Swallow the tablets with some water.
Read the package leaflet before use.

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 *(overprinted)*

9. SPECIAL STORAGE CONDITIONS

Keep the blister in the outer carton in order to protect from moisture.
Do not store above 25° C.

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

IVAX Pharmaceuticals UK, Ridings Point, Castleford WF10 5HX

12. MARKETING AUTHORISATION NUMBER(S)

PL 00530/0764

13. BATCH NUMBER

BN *(overprinted)*

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medicinal prescription

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Perindopril 2 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

Perindopril 2 mg Tablets
Perindopril tert-butylamine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

IVAX Pharmaceuticals UK

3. EXPIRY DATE

EXP *(overprinted)*

4. BATCH NUMBER

BN *(overprinted)*

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Perindopril 4 mg Tablets
Perindopril tert-butylamine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains perindopril tert-butylamine 4 mg equivalent to 3.338 mg perindopril.

3. LIST OF EXCIPIENTS

Contains lactose, see leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

14 Tablets
15 tablets
30 Tablets
60 Tablets
90 Tablets
120 Tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Swallow the tablets with some water.
Read the package leaflet before use.

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 *(overprinted)*

9. SPECIAL STORAGE CONDITIONS

Keep the blister in the outer carton in order to protect from moisture.
Do not store above 25° C.

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

IVAX Pharmaceuticals UK, Ridings Point, Castleford WF10 5HX

12. MARKETING AUTHORISATION NUMBER(S)

PL 00530/0765

13. BATCH NUMBER

BN *(overprinted)*

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medicinal prescription

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Perindopril 4 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

Perindopril 4 mg Tablets
Perindopril tert-butylamine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

IVAX Pharmaceuticals UK

3. EXPIRY DATE

EXP *(overprinted)*

4. BATCH NUMBER

BN *(overprinted)*

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Perindopril 8 mg Tablets
Perindopril tert-butylamine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains perindopril tert-butylamine 8 mg equivalent to 6.676 mg perindopril.

3. LIST OF EXCIPIENTS

Contains lactose, see leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

14 Tablets
15 tablets
30 Tablets
60 Tablets
90 Tablets
120 Tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Swallow the tablets with some water.
Read the package leaflet before use.

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 *(overprinted)*

9. SPECIAL STORAGE CONDITIONS

Keep the blister in the outer carton in order to protect from moisture.
Do not store above 25° C.

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

IVAX Pharmaceuticals UK, Ridings Point, Castleford WF10 5HX

12. MARKETING AUTHORISATION NUMBER(S)

PL 00530/0766

13. BATCH NUMBER

BN *(overprinted)*

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medicinal prescription

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Perindopril 8 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

Perindopril 8 mg Tablets
Perindopril tert-butylamine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

IVAX Pharmaceuticals UK

3. EXPIRY DATE

EXP *(overprinted)*

4. BATCH NUMBER

BN *(overprinted)*

5. OTHER

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, commitmen

Date submitted	Application type	Scope	Outcome
22/02/2018	Type IB	To update sections 4.2 and 5.1 of the Summaries of Product Characteristics (SmPCs) in line with Article 46 of Regulation EC No1901/2006 wordings. Consequently, the Patient Information Leaflet (PIL) has been updated.	Approved on 06 April 2018

Annex 1

Reference: **PL 00530/0764 – 0053, PL 00530/0765 – 0053 and PL 00530/0766 - 0051**

Product: **Perindopril 2 mg, 4 mg and 8 mg Tablets**

Marketing Authorisation Holder: **Norton Healthcare Limited**

Active Ingredient: **perindopril tert-butylamine**

Reason:
To update sections 4.2 and 5.1 of the Summaries of Product Characteristics (SmPCs) in line with Article 46 of Regulation EC No1901/2006 wordings. Consequently, the Patient Information Leaflet (PIL) has been updated.

Supporting evidence
The applicant has submitted updated sections of the SmPCs.

Evaluation
The amended Section 4.2 and 5.1 of the SmPCs are satisfactory.

Conclusion
The updated SmPC fragments have been incorporated into these Marketing Authorisations. The proposed change is acceptable.

Decision: Grant
Date: 06 April 2018