Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Public Assessment Report

UKPAR

LOSARTAN POTASSIUM 25 MG FILM-COATED TABLETS
LOSARTAN POTASSIUM 50 MG FILM-COATED TABLETS
LOSARTAN POTASSIUM 100 MG FILM-COATED TABLETS
(losartan potassium)

UK Licence Number: PL 20416/0489-90 & 0565

Crescent Pharma Limited

Medicines and Healthcare Products Regulatory Agency

LAY SUMMARY
Losartan potassium 25 mg Film-coated tablets
Losartan potassium 50 mg Film-coated tablets
Losartan potassium 100 mg Film-coated tablets
(losartan potassium)

This is a summary of the Public Assessment Report (PAR) for Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets (PL 20416/0489-90 and 0565).

This summary explains how Losartan potassium 25 mg, 50 mg and 100 mg Film-coated 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 these products.

For practical information about using Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets, patients should read the Patient Information Leaflet (PIL) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website or contact their doctor or pharmacist.

What are Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets and what are they used for?

These medicines are the same as Losartan potassium 25 mg, 50 mg and 100 mg film-coated tablets (PL 19156/0053-55) which have already been authorised. The company (Jubilant Pharmaceuticals NV) that make Losartan potassium 25 mg, 50 mg and 100 mg film-coated tablets (PL 19156/0053-55) has provided its scientific data as a basis for the grant of identical licences for Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets (PL 20416/0489-90, 0565; informed consent).

Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets are used:

- to treat patients with high blood pressure (hypertension) in adults and in children and adolescents 6-18 years of age.
- to protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria ≥0.5g per day (a condition in which urine contains an abnormal amount of protein).
- to treat patients with chronic heart failure when therapy with specific medicines called angiotensin-converting-enzyme inhibitors (ACE inhibitors, medicine used to lower high blood pressure) is not considered suitable by your doctor. If the patient's heart failure has been stabilised with an ACE inhibitor they should not be switched to losartan.
- in patients with high blood pressure and a thickening of the left ventricle, Losartan potassium tablets have been shown to decrease the risk of stroke ("LIFE indication").

How do Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets work?

These medicines contain the active ingredient losartan potassium, which belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body, which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevents the binding of Angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

How are Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets used?

These medicines can only be obtained with a prescription.

A doctor will decide on the appropriate dose of Losartan potassium tablets, depending on the condition and whether the patient is taking other medicines. It is important for patients to continue taking Losartan potassium tablets for as long as the doctor prescribes it, in order to maintain smooth control of their

blood pressure. The tablets should be swallowed with a glass of water. Patients should try to take the daily dose at about the same time each day. It is important that patients continue to take Losartan potassium tablets until their doctor tells them otherwise.

In adult patients with high blood pressure, treatment usually starts with 50mg losartan (one tablet of Losartan potassium 50 mg) once a day. The maximal blood pressure lowering effect should be reached 3-6 weeks after beginning treatment. In some patients the dose may later be increased to 100 mg losartan potassium (two tablets of Losartan potassium 50mg or one tablet of Losartan potassium 100 mg) once daily. If the patient has the impression that the effect of losartan is too strong or too weak, they should talk to their doctor or pharmacist.

In children below 6 years of age, Losartan potassium tablets are not recommended for use, as they have not been shown to work in this age group.

In children aged 6-18 years old, the recommended starting dose in patients who weigh between 20 and 50 kg is 0.7 mg of losartan per kg of body weight administered once a day (up to 25 mg losartan). The doctor may increase the dose if blood pressure is not controlled. Other form(s) of this medicine may be more suitable for children; patients should ask their doctor or pharmacist.

In adult patients with high blood pressure and Type II diabetes, treatment usually starts with 50 mg losartan potassium (one tablet of Losartan potassium 50 mg) once a day. The dose may later be increased to 100 mg losartan (two tablets of Losartan potassium 50 mg or one tablet of Losartan potassium 100 mg) once daily depending on the blood pressure response. Losartan may be administered with other blood pressure lowering medicines (e.g. diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used medicines that decrease the level of glucose in the blood (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

In adult patients with heart failure, treatment usually starts with 12.5 mg losartan potassium (one tablet of Losartan potassium 12.5 mg) once a day. Generally, the dose should be increased weekly step-by-step (i.e., 12.5 mg daily during the first week, 25 mg daily during the second week, 50 mg daily during the third week, 100 mg daily during the fourth week, 150 mg daily during the fifth week) up to the maintenance dose as determined by the doctor. A maximum dose of 150 mg losartan (for example, three tablets of Losartan potassium 50 mg or one tablet each of Losartan potassium 100 mg and Losartan potassium 50 mg) once daily may be used.

In the treatment of heart failure, losartan is usually combined with a diuretic (medicine that increases the amount of water that passes out through the kidneys) and/or digitalis (medicine that helps to make the heart stronger and more efficient) and/or a beta-blocker.

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those treated with diuretics in high doses, in patients with liver impairment, or in patients over the age of 75 years. The use of losartan is not recommended in patients with severe hepatic impairment.

How have Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets been studied?
Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets are considered identical to Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets (PL 19156/0053-55; Jubilant Pharmaceuticals NV), with the same benefits and risks.

No new studies have been provided for Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets but reference is made to the studies for Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets (PL 19156/0053-55).

What are the possible side effects of Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The applications for Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets are considered to be identical to Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets (PL 19156/0053-55; Jubilant Pharmaceuticals) with the same benefits and risks.

For a full list of all the side effects reported with Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets see section 4 of the patient information leaflet (PIL), available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

For the full list of restrictions, see the patient information leaflet (PIL).

Why are Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets approved?

No new or unexpected safety concerns arose from these applications. The MHRA, therefore, considered that the benefits of Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets outweigh their risks; and the grant of Marketing Authorisations was recommended.

What measures are being taken to ensure the safe and effective use of Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets?

A Risk Management Plan (RMP) has been developed to ensure that Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets are used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics (SmPCs) and the patient information leaflet (PIL) for Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets, including the appropriate precautions to be followed by patients.

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 Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets

The UK granted Marketing Authorisations for Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets on 11 September 2018.

The full PAR for Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets follows this summary. For more information about treatment with Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets, read the patient information leaflet (PIL) or the patient should contact their doctor or pharmacist.

This summary was last updated in October 2018.

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(losartan potassium)

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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA considered that the applications for Losartan potassium 25 mg, 50 mg and 100 mg Film-coated tablets (PL 20416/0489-90 and 0565) could be approved. The products are prescription only medicines (legal status POM) indicated as follows:

- Treatment of essential hypertension in adults and in children and adolescents 6-18 years of age.
- Treatment of renal disease in adult patients with hypertension and type 2 diabetes mellitus with proteinuria ≥ 0.5 g/day as part of an antihypertensive treatment
- Treatment of chronic heart failure (in patients ≥ 60 years), when treatment with ACE inhibitors is not considered suitable due to incompatibility, especially cough, or contraindication. Patients with heart failure who have been stabilised with an ACE inhibitor should not be switched to losartan. The patients should have a left ventricular ejection fraction ≤ 40% and should be stabilised under the treatment of the chronic heart failure.
- Reduction in the risk of stroke in adult hypertensive patients with left ventricular hypertrophy documented by ECG.

These applications were made under Article 10c of Directive 2001/83/EC, as amended, claiming to be identical to the cross-referenced products Losartan potassium 25 mg, 50 mg and 100 mg film-coated tablets (PL 19156/0053-55) which were granted Marketing Authorisations to Jubilant Pharmaceuticals NV. on 01 March 2010.

No new non-clinical or clinical studies were conducted, which is acceptable given that the applications are for products which are identical to products that have been granted Marketing Authorisations in the UK.

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

A satisfactory summary of the pharmacovigilance system and risk management plan has been provided with this application.

National Marketing Authorisations were granted in the UK on 11 September 2018.

II QUALITY ASPECTS

II.1 INTRODUCTION

These are simple, informed consent applications for Losartan potassium 25, 50 and 100 mg Film-coated tablets, submitted under Article 10c of Directive 2001/83/EC, as amended.

II.2. Drug Substance

The proposed drug substance specification is consistent with the details registered for the cross-referenced products.

II.3. Medicinal Product Name

The following product names are proposed: Losartan potassium 25, 50 and 100 mg Film-coated tablets. The products have been named in line with current requirements.

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

Each Losartan potassium 25 mg Film-coated tablet contains 25 mg of losartan potassium.
Each Losartan potassium 50 mg Film-coated tablet contains 50 mg of losartan potassium.
Each Losartan potassium 100 mg Film-coated tablet contains 100 mg of losartan potassium.

The route of administration is oral.

The finished product is packaged in polyvinyl chloride/polyethylene/polyvinylidene chloride-aluminium blister packs in cartons containing 28 tablets.

The proposed shelf life is 3 years, with no special storage conditions. The proposed packaging and shelf life are consistent with the details registered for the cross-reference products.

Legal status

On approval, these products will be available as prescription only medicines (legal status POM).

Marketing authorisation holder/Contact Persons/Company

Crescent Pharma Limited, Units 3 and 4, Quidhampton Business Units, Polhampton Lane, Overton, Hampshire, RG25 3ED, United Kingdom.

Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-referenced products and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

Qualitative and quantitative composition

The composition is consistent with the details registered for the cross-referenced products.

Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-referenced products.

Finished product/shelf-life specification

The proposed finished product specification is in line with the details registered for the cross-referenced products.

Drug substance specification

The proposed drug substance specification is consistent with the details registered for the cross-referenced products.

TSE Compliance
With the exception of the excipient lactose monohydrate, no materials of animal or human origin are included in these products. This is consistent with the cross-referenced products. The lactose monohydrate is produced from milk that has been sourced from healthy cows in the same conditions as milk collected for human consumption.

These products do not contain or consist of genetically modified organisms (GMO).

Expert Report
The applicant has included expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

Product Name and Appearance
See section 'II.3. Medicinal Product Name' for details of the proposed product name. The appearance of the products is identical to the cross-referenced products.

Summary of Product Characteristics (SmPC)

The proposed SmPCs are consistent with the details registered for the cross-referenced products.

II.4 Discussion on pharmaceutical aspects

The grant of Marketing Authorisations is recommended.

III NON-CLINICAL ASPECTS

Introduction

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

Ecotoxicity/Environmental Risk Assessment (ERA)

Since these products will be used in substitution for other products that are currently on the market, this will not lead to an increase of the environmental exposure. An ERA is, therefore, not deemed necessary.

Discussion on the non-clinical aspects

The grant of Marketing Authorisations is recommended.

IV CLINICAL ASPECTS

Introduction

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

The SmPCs and PIL are consistent with those of the cross-referenced product.

The Marketing Authorisation Holder (MAH) 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 Qualified Person (QP) responsible for pharmacovigilance is stated and their Curriculum Vitae (CV) is included.

Risk Management Plan (RMP)

The Marketing Authorisation Holder (MAH) has submitted a Risk Management Plan (RMP), in accordance with the requirements of Directive 2001/83/EC, as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to the use of these products. A summary of safety concerns, as approved in the RMP, is listed below:

Safety concern	Routine risk minimisation measures	Additional risk minimisation measures
Hypersensitivity reactions	Labelling: Sufficient information regarding hypersensitivity reactions is included in: **Contraindication in section 4.3** **Special warnings and precautions for use in section 4.4** **Undesirable effects in section 4.8** All routine risk minimisation measures will be carried out. The same risks are mentioned in lay terms under the corresponding section of the PIL. • Prescription only medicine	None proposed
Symptomatic hypotension	Labelling: Sufficient information regarding symptomatic hypotension is included in: **Special warnings and precautions for use in section 4.4** **Interaction with other medicinal products and other forms of interaction in section 4.5** **Fertility, pregnancy and lactation in section 4.6** **Undesirable effects in section 4.8** **Overdose in section 4.9** **Pharmacodynamic properties in section 5.1** All routine risk minimisation measures will be carried out. The same risks are mentioned in lay terms under the corresponding section of the PIL. • Prescription only medicine	None proposed
Hyperkalaemia	Labelling: Sufficient information regarding electrolyte imbalances, including hyperkalaemia is included in: **Special warnings and precautions for use in section 4.4** **Interaction with other medicinal products and other forms of interaction in section 4.5** **Fertility, pregnancy and lactation in section 4.6** **Undesirable effects in section 4.8:** **Pharmacodynamic properties in section 5.1** All routine risk minimisation measures will be carried out. The same risks are mentioned in lay terms under the corresponding section of the PIL. • Prescription only medicine	None proposed

Safety concern	Routine risk minimisation measures	Additional risk minimisation measures
Renal impairment, including renal failure	Labelling: Sufficient information regarding renal impairment is included in: **Contraindications in section 4.3** **Special warnings and precautions for use in section 4.4** **Interaction with other medicinal products and other forms of interaction in section 4.5** **Undesirable effects in section 4.8** **Pharmacodynamic properties in section 5.1** All routine risk minimisation measures will be carried out. The same risks are mentioned in lay terms under the corresponding section of the PIL. • Prescription only medicine	None proposed
Dual blockade of the renin-angiotensin-aldosterone system (RAAS)	Labelling: Sufficient information regarding dual blockade of the renin-angiotensin-aldosterone system is included in: **Contraindications in section 4.3** **Special warnings and precautions for use in section 4.4** **Interaction with other medicinal products and other forms of interaction in section 4.5** **Pharmacodynamic properties in section 5.1** All routine risk minimisation measures will be carried out. The same risks are mentioned in lay terms under the corresponding section of the PIL. • Prescription only medicine	Link for CHMP opinion dated from 9 September 2014 on Annex 12 (EMA/554928/2014)
Use in pregnancy	Labelling: Sufficient information regarding the use in 2nd and 3rd trimester of pregnancy is included in: **Contraindications in section 4.3** **Special warnings and precautions for use in section 4.4** **Fertility, pregnancy and lactation in section 4.6** **Preclinical safety data in section 5.3** All routine risk minimisation measures will be carried out. The same risks are mentioned in lay terms under the corresponding section of the PIL. • Prescription only medicine	None proposed
Concomitant administration	Labelling: Sufficient information regarding the concomitant administration with lithium is included in:	None proposed

Safety concern	Routine risk minimisation measures	Additional risk minimisation measures
with lithium	**Interaction with other medicinal products and other forms of interaction in section 4.5** All routine risk minimisation measures will be carried out. The same risks are mentioned in lay terms under the corresponding section of the PIL. • Prescription only medicine	
Use in patients with severe hepatic impairment	Labelling: Sufficient information regarding the use in patients with severe hepatic impairment is included in: **Posology and method of administration in section 4.2** **Contraindications in section 4.3** **Special warnings and precautions for use in section 4.4** All routine risk minimisation measures will be carried out. The same risks are mentioned in lay terms under the corresponding section of the PIL. • Prescription only medicine	None proposed
Use in patients with renal transplantation	Labelling: Sufficient information regarding the use in patients with renal transplantation is included in: **Special warnings and precautions for use in section 4.4** All routine risk minimisation measures will be carried out. The same risks are mentioned in lay terms under the corresponding section of the PIL. • Prescription only medicine	None proposed
Use in children under 6 years old or with renal / hepatic impairment	Labelling: Sufficient information regarding the use in children under 6 years old and in children with renal or hepatic impairment is included in: **Posology and method of administration in section 4.2** **Special warnings and precautions for use in section 4.4** **Undesirable effects in section 4.8** All routine risk minimisation measures will be carried out. The same risks are mentioned in lay terms under the corresponding section of the PIL. • Prescription only medicine	None proposed
Use during breastfeeding	Labelling: Sufficient information regarding the use during breastfeeding is included in: **Fertility, pregnancy and lactation in section 4.6:**	None proposed

Safety concern	Routine risk minimisation measures	Additional risk minimisation measures
	All routine risk minimisation measures will be carried out. The same risks are mentioned in lay terms under the corresponding section of the PIL. • Prescription only medicine	

Routine pharmacovigilance and routine risk minimisation are proposed for all safety concerns.

Discussion on the clinical aspects

The grant of Marketing Authorisations is recommended.

V User consultation

The results of consultations with target patient groups ('user testing'), in accordance with Article 59 of Council Directive 2001/83/EC, as amended, have been provided. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

VI Overall conclusion, benefit/risk assessment and recommendation

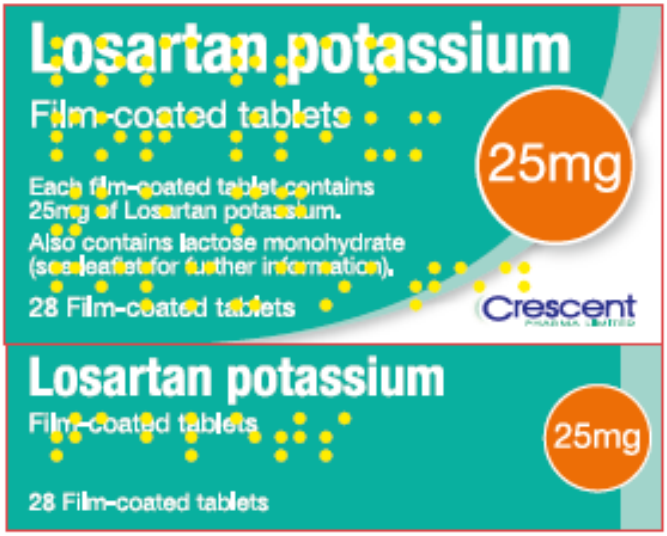
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. These products are identical to the current granted products Losartan potassium 25 mg, 50 mg and 100 mg film-coated tablets (PL 19156/0053-55; Jubilant Pharmaceuticals NV). The benefit/risk assessment is, therefore, considered to be positive.

In accordance with Directive 2010/84/EU, the current approved UK versions of the SmPCs and PIL for these products are available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

The approved labels are shown below:


Losartan potassium
Film-coated tablets
25mg
28 Film-coated tablets
Losartan potassium
Film-coated tablets
25mg
Losartan potassium 25mg Film-coated tablets
For oral use as directed by the doctor.
Please read the leaflet provided before use.
28 Film-coated tablets
Place dispensing label here


Crescent Pharma Ltd
LOSARTAN POTASSIUM 25mg Film-coated tablets


Losartan potassium
Film-coated tablets
25mg
Each film-coated tablet contains 25mg of Losartan potassium.
Also contains lactose monohydrate (see leaflet for further information).
28 Film-coated tablets
Crescent
Losartan potassium
Film-coated tablets
25mg
28 Film-coated tablets


Losartan potassium
Film-coated tablets
50mg
28 Film-coated tablets
Losartan potassium
Film-coated tablets
50mg
Each film-coated tablet contains
50mg of Losartan potassium.
Also contains lactose monohydrate
(see leaflet for further information).
28 Film-coated tablets
Crescent PHARMA LIMITED
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Product Licence holder:
Crescent Pharma Ltd,
Pollamphton Lane, Overton,
Hampshire RG25 3ED, UK
POM
PL 20416/0490
Losartan potassium 50mg Film-coated tablets
For oral use as directed by the doctor.
Please read the leaflet provided before use.
Place dispensing label here
28 Film-coated tablets


Crescent Pharma Ltd
LOSARTAN POTASSIUM 50mg Film-coated tablets
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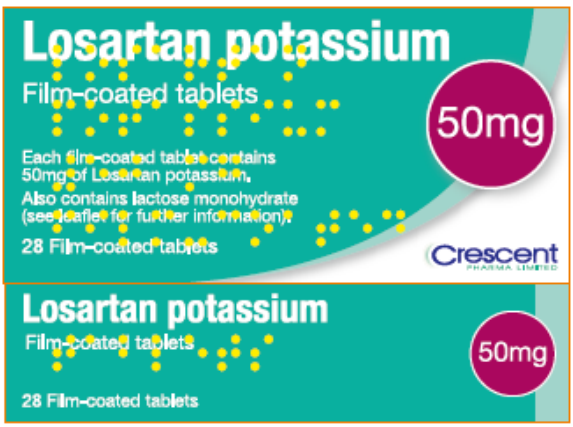
Losartan potassium
Film-coated tablets
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50mg of Losartan potassium.
Also contains lactose monohydrate
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Crescent PHARMA LIMITED
Losartan potassium
Film-coated tablets
50mg
28 Film-coated tablets


28 Film-coated tablets
100mg
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(see leaflet for further information).
28 Film-coated tablets
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KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Product Licence holder:
Crescent Pharma Ltd,
Pollamphton Lane, Overton,
Hampshire RG25 3ED, UK
POM
PL 20416/0565
Losartan potassium 100mg Film-coated tablets
For oral use as directed by the doctor.
Please read the leaflet provided before use.
Place dispensing label here
28 Film-coated tablets


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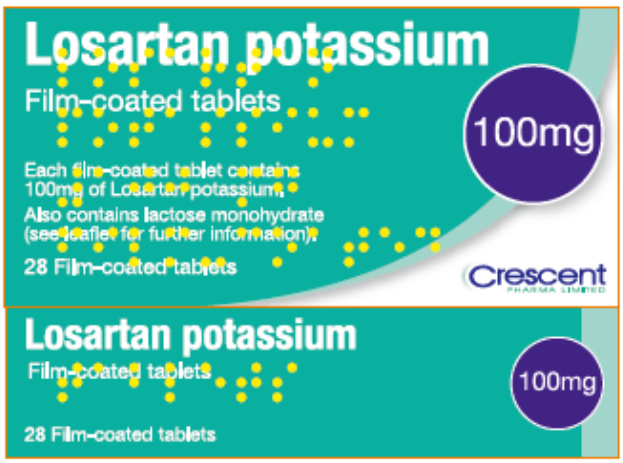
Losartan potassium
Film-coated tablets
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Each film-coated tablet contains
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Also contains lactose monohydrate
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28 Film-coated tablets
Crescent
Losartan potassium
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Table of content of the PAR update

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitments)

Date submitted	Application type	Scope	Outcome