Public Assessment Report

Decentralised Procedure

Atorvastatin 10 mg film-coated tablets
Atorvastatin 20 mg film-coated tablets
Atorvastatin 40 mg film-coated tablets

(Atorvastatin calcium trihydrate)

Procedure No: UK/H/5953/001-3/DC

UK Licence Number: PL 41947/0009-11

ELC Group s.r.o.
LAY SUMMARY

Atorvastatin 10 mg, 20 mg and 40 mg film-coated tablets

(atorvastatin calcium trihydrate, film-coated tablet, 10 mg, 20 mg and 40 mg)

This is a summary of the Public Assessment Report (PAR) for Atorvastatin 10 mg, 20 mg and 40 mg film-coated tablets (PL 41947/0009-11; UK/H/5953/001-3/DC). It explains how Atorvastatin 10 mg, 20 mg and 40 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 Atorvastatin 10 mg, 20 mg and 40 mg film-coated tablets.

The products will be collectively referred to as Atorvastatin throughout the remainder of this public assessment report (PAR).

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

What is Atorvastatin and what is it used for?
Atorvastatin is a ‘generic medicine’. This means that Atorvastatin is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Lipitor 10 mg, 20 mg and 40 mg film-coated tablets (Pfizer Ireland Pharmaceuticals).

Atorvastatin is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and lifestyle changes on their own have failed. If the patient is at an increased risk of heart disease, Atorvastatin can also be used to reduce such risk even if the patient’s cholesterol levels are normal. The patient should maintain a standard cholesterol lowering diet during treatment.

How does Atorvastatin work?
Atorvastatin belong to a group of medicines called statins, which are lipid (fat) regulating medicines. Statins lower blood cholesterol (and triglycerides).

How is Atorvastatin used?
The pharmaceutical form of this medicine is a film-coated tablet and the route of administration is oral (by mouth).

The patient must always take this medicine exactly as their doctor has told them. The patient should check with their doctor or pharmacist if they are not sure.

Before starting treatment, the patient’s doctor will place the patient on a low-cholesterol diet, which they should maintain also during therapy with this medicine. The usual starting dose is 10 mg of atorvastatin once a day in adults and children aged 10 years or older. This may be increased if necessary by the patient’s doctor until the patient is taking the amount they need. The patient’s doctor will adapt the dose at intervals of 4 weeks or more. The maximum dose of atorvastatin is 80 mg once daily for adults and 20 mg once daily for children.

The tablets should be swallowed whole with a drink of water and can be taken at any time of day, with or without food.

Please read section 3 of the package leaflet for detailed dosing recommendations, the route of administration, and the duration of treatment.
For further information on how Atorvastatin is used, refer to the package leaflet and Summary of Product Characteristics available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

**What benefits of Atorvastatin have been shown in studies?**
Because Atorvastatin is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine Lipitor 10 mg, 20 mg and 40 mg film-coated tablets (Pfizer Ireland Pharmaceuticals). Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

**What are the possible side effects of Atorvastatin?**
Because Atorvastatin is a generic medicine and is bioequivalent to the reference medicine Lipitor 10 mg, 20 mg and 40 mg film-coated tablets (Pfizer Ireland Pharmaceuticals), its benefits and possible side effects are taken as being the same as the reference medicine.

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

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

**Why was Atorvastatin approved?**
It was concluded that, in accordance with EU requirements, Atorvastatin has been shown to have comparable quality and to be bioequivalent to Lipitor 10 mg, 20 mg and 40 mg film-coated tablets (Pfizer Ireland Pharmaceuticals). Therefore, the MHRA decided that, as for Lipitor 10 mg, 20 mg and 40 mg film-coated tablets (Pfizer Ireland Pharmaceuticals); the benefits are greater than the risks and recommended that they can be approved for use.

**What measures are being taken to ensure the safe and effective use of Atorvastatin?**
A risk management plan (RMP) has been developed to ensure that Atorvastatin is used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics (SmPCs) and the package leaflet for Atorvastatin 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/reviewed continuously.

**Other information about Atorvastain**
Germany and the UK agreed to grant Marketing Authorisations for Atorvastatin on 16 February 2016. Marketing Authorisations were granted in the UK on 17 March 2016.

The full PAR for Atorvastatin follows this summary.

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

This summary was last updated in May 2016.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I Introduction</td>
<td>5</td>
</tr>
<tr>
<td>II Quality aspects</td>
<td>7</td>
</tr>
<tr>
<td>III Non-clinical aspects</td>
<td>9</td>
</tr>
<tr>
<td>IV Clinical aspects</td>
<td>9</td>
</tr>
<tr>
<td>V User consultation</td>
<td>11</td>
</tr>
<tr>
<td>VI Overall conclusion, benefit/risk assessment and recommendation</td>
<td>11</td>
</tr>
</tbody>
</table>
I  INTRODUCTION
Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) granted ELC Group s.r.o, marketing authorisations for the medicinal products Atorvastatin (PL 41947/0009-11; UK/H/5953/001-3/DC) The products are prescription-only medicines (POM) indicated for:

Hypercholesterolaemia
Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate.

Atorvastatin is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.

Prevention of cardiovascular disease
Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event (see section 5.1), as an adjunct to correction of other risk factors

The applications were submitted using the Decentralised Procedure (DCP), with the UK as Reference Member State (RMS), and Germany as Concerned Member State (CMS). The applications were submitted under Article 10(1) of Directive 2001/83/EC, as amended, as generic applications. The reference medicinal products for these applications are Lipitor 10 mg, 20 mg and 40 mg film-coated tablets which were authorised to Pfizer Manufacturing Ireland (PL 16051/0001-3) on 08 September 1997 and underwent a change of ownership procedure to the current marketing authorisation holder (MAH) Pfizer Ireland Pharmaceuticals (PL 39933/0001-3) on 12 September 2011.

Atorvastatin is a selective, competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme responsible for the conversion of 3-hydroxy-3-methyl-glutaryl-coenzyme A to mevalonate, a precursor of sterols, including cholesterol. Triglycerides and cholesterol in the liver are incorporated into very low-density lipoproteins (VLDL) and released into the plasma for delivery to peripheral tissues. Low-density lipoprotein (LDL) is formed from VLDL and is catabolised primarily through the receptor with high affinity to LDL (LDL receptor).

Atorvastatin lowers plasma cholesterol and lipoprotein serum concentrations by inhibiting HMG-CoA reductase and subsequently cholesterol biosynthesis in the liver and increases the number of hepatic LDL receptors on the cell surface for enhanced uptake and catabolism of LDL.

Atorvastatin reduces LDL production and the number of LDL particles. Atorvastatin produces a profound and sustained increase in LDL receptor activity coupled with a beneficial change in the quality of circulating LDL particles. Atorvastatin is effective in reducing LDL-C in patients with homozygous familial hypercholesterolaemia, a population that has not usually responded to lipid-lowering medicinal products.

Atorvastatin has been shown to reduce concentrations of total-C (30% - 46%), LDL-C (41% - 61%), apolipoprotein B (34% - 50%), and triglycerides (14% - 33%) while producing variable increases in HDL-C and apolipoprotein A1 in a dose response study. These results are consistent in patients with heterozygous familial hypercholesterolaemia, nonfamilial forms of hypercholesterolaemia, and mixed hyperlipidaemia, including patients with noninsulin-dependent diabetes mellitus.
Reductions in total-C, LDL-C, and apolipoprotein B have been proven to reduce risk for cardiovascular events and cardiovascular mortality.

One bioequivalence study (conducted under fasting conditions) was submitted to support these applications. The applicant has stated that the bioequivalence study was conducted in accordance with the protocol and all the other pertinent requirements of the ICH- Good Clinical Practice, Schedule Y and the principles enunciated in the Declaration of Helsinki (The WMA General Assembly, 2013).

With the exception of the bioequivalence study, no new non-clinical or clinical data were submitted, which is acceptable given that these applications were based on being a generic medicinal product of an originator product that has been in clinical use for over 10 years.

The RMS has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product type at all sites responsible for the manufacture, assembly and batch release of these products.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the Community, the RMS has accepted copies of current GMP Certificates of 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.

The RMS and CMS considered that the applications could be approved at the end of procedure on 16 February 2016. After a subsequent national phase, licences were granted in the UK on 17 March 2016.
II QUALITY ASPECTS

II.1 Introduction
Each film-tablet contains 10 mg, 20 mg or 40 mg atorvastatin as atorvastatin calcium trihydrate, as the active ingredient. Other ingredients consist of the pharmaceutical excipients:

**Tablet core:**
Calcium carbonate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose and magnesium stearate.

**Film coat:**
Opadry YS-1-7040 white [consisting of hypromellose (E464), macrogol 8000 (E1521), titanium dioxide (E171) and talc (E553b)].

All strengths of the finished product are packed in to the following presentations and pack sizes:
- Blister packs containing 10, 20, 30, 50, 90 and 100 film-coated tablets
- High-density polyethylene (HDPE) bottles containing 30 and 100 film-coated tablets.
Not all pack sizes may be marketed.

The blisters consist of a forming film made of polyamide/aluminium foil/polyvinyl chloride and a backing made of either paper/polyester/aluminium foil/vinyl heat-seal coating or aluminium foil/vinyl heat-seal coating.

The bottle is made of HDPE, containing desiccant, with squeeze-and-turn child-resistant closure.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components.

II.2 Drug Substance

INN: Atorvastatin calcium trihydrate
Chemical name: Calcium (3R,5R)-7-[2-(4-fluorophenyl)-5-(1-methylethyl)-3-phenyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoate trihydrate.

Structure:

![Structure diagram](image)

Molecular formula: C_{66}H_{68}CaF_{2}N_{4}O_{10,3}H_{2}O
Molecular weight: 1209 g/mol
Description: White or almost white powder.
Solubility: Very slightly soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride.

Atorvastatin calcium trihydrate is the subject of a European Pharmacopoeia monograph.
All aspects of the manufacture and control of the active substance, atorvastatin calcium trihydrate, are covered by the European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

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 film-coated tablets containing 10 mg, 20 mg or 40 mg atorvastatin as atorvastatin calcium trihydrate per tablet, that are generic versions of the reference products Lipitor 10 mg, 20 mg and 40 mg film-coated tablets (Pfizer Ireland Pharmaceuticals). A satisfactory account of the pharmaceutical development has been provided.

Comparative in-vitro dissolution and impurity profiles have been provided for the proposed and originator products.

All excipients comply with their respective European Pharmacopoeia monographs with the exception of the film coat Opadry YS-1-7040 white which is controlled to a suitable in-house specification. Satisfactory Certificates of Analysis have been provided for all excipients. Suitable batch analysis data have been provided for each excipient.

With the exception of lactose monohydrate none of the excipients used contain material of animal or human origin. The supplier of lactose monohydrate has confirmed that it is sourced from healthy animals under the same conditions as milk for human consumption.

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

Manufacture of the product

Satisfactory batch formulae have been provided for the manufacture of the products, along with an appropriate account of the manufacturing process. The manufacturing process has been validated at pilot scale batch size and has shown satisfactory results. The marketing authorisation holder (MAH) has committed to perform additional process validation studies on future commercial-scale batches.

Finished Product Specification

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

Stability of the Product

Finished product stability studies were performed in accordance with current guidelines on batches of the finished product in the packaging proposed for marketing. The data from these studies support a shelf-life of 2 years with the storage condition ‘Store below 25°C.’

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

II.4 Discussion on chemical, pharmaceutical and biological aspects

There are no objections to the approval of these applications from a pharmaceutical viewpoint.
III  NON-CLINICAL ASPECTS

III.1  Introduction
As the pharmacodynamic, pharmacokinetic and toxicological properties of atorvastatin are well-known, no new non-clinical studies are required and none have been provided. An overview based on the literature review is, thus, appropriate.

The applicant’s non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

III.2  Pharmacology
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

III.3  Pharmacokinetics
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

III.4  Toxicology
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

III.5  Ecotoxicity/environmental risk assessment (ERA)
Since Atorvastatin is intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

III.6  Discussion on the non-clinical aspects
No new non-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.

There are no objections to the approval of these applications from a non-clinical viewpoint.

IV  CLINICAL ASPECTS

IV.1  Introduction
The clinical pharmacology of atorvastatin is well-known. With the exception of data from the bioequivalence study detailed below, no new pharmacodynamics or pharmacokinetic data are provided or are required for these applications.

No new efficacy or safety 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, citing the well-established clinical pharmacology, efficacy and safety of atorvastatin.

Based on the data provided, Atorvastatin can be considered bioequivalent to Lipitor 10 mg, 20 mg and 40 mg film-coated tablets (Pfizer Ireland Pharmaceuticals).

IV.2  Pharmacokinetics
In support of these applications, the applicant submitted the following bioequivalence study:

STUDY
An open-label, balanced, randomised, single-dose, two-treatment, two sequence, two-period, crossover, oral bioequivalence study of the applicant’s test product Atorvastatin 40 mg film-coated tablets (ELC Group s.r.o., Czech Republic) versus the reference product Lipitor 40 mg film-coated tablets (Pfizer Ireland Pharmaceuticals) in healthy, adult, subjects under fasting conditions.
Following an overnight fast of at least 10 hours, subjects were administered a single dose (1 x 40 mg tablet) of the test or the reference product with 240 mL of water.

Blood samples were collected for plasma levels before dosing and up to and including 96 hours after each administration. The washout period between the treatment phases was 15 days. The pharmacokinetic results are presented below:

**Table: Descriptive Statistics of Pharmacokinetic Parameters of Atorvastatin under fasting conditions:**

<table>
<thead>
<tr>
<th>PK Parameter</th>
<th>Test Product</th>
<th>Reference product</th>
</tr>
</thead>
<tbody>
<tr>
<td>$C_{\text{max}}$ (ng/mL)</td>
<td>45.07 (11.22-158.03)</td>
<td>47.93 (13.36-198.78)</td>
</tr>
<tr>
<td>AUC$_{0-96}$ (ng.hr/mL)</td>
<td>201.77 (67.93-532.59)</td>
<td>213.36 (89.07-856.59)</td>
</tr>
<tr>
<td>AUC$_{0-\infty}$ (ng.hr/mL)</td>
<td>205.53 (69.84-535.74)</td>
<td>216.74 (92.83-859.53)</td>
</tr>
<tr>
<td>$T_{\text{max}}$ (hours)</td>
<td>1.36 (0.5-4.5)</td>
<td>1.2 (0.5-4.5)</td>
</tr>
</tbody>
</table>

**Table: Ln-transformed Pharmacokinetic Parameters for Atorvastatin under fasting conditions:**

<table>
<thead>
<tr>
<th>Variable</th>
<th>(T/R) Ratio %</th>
<th>90% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>$C_{\text{max}}$ (ng/mL)</td>
<td>96.00</td>
<td>87.83 - 104.92</td>
</tr>
<tr>
<td>AUC$_{0-96}$ (ng.hr/mL)</td>
<td>96.71</td>
<td>92.85 - 100.73</td>
</tr>
<tr>
<td>AUC$_{0-\infty}$ (ng.hr/mL)</td>
<td>96.94</td>
<td>93.14 - 100.90</td>
</tr>
</tbody>
</table>

AUC$_{0-96}$ area under the plasma concentration-time curve from zero to 96 hours
AUC$_{0-\infty}$ area under the plasma concentration-time curve from time zero to infinity
$C_{\text{max}}$ maximum plasma concentration

**Conclusion**

The 90% confidence intervals of the test/reference ratio for AUC and $C_{\text{max}}$ values for atorvastatin for the 40 mg test product strength 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 Atorvastatin 40 mg film-coated tablets (ELC Group s.r.o., Czech Republic) is bioequivalent to the reference product Lipitor 40 mg film-coated tablets (Pfizer Ireland Pharmaceuticals).

As the 10 mg, 20 mg and 40 mg strength test products meet the biowaiver criteria specified in the current bioequivalence guidance, the results and conclusions of the bioequivalence study with the 40 mg tablet strength can be extrapolated to the 10 mg and 20 mg strength tablets.

**IV.3 Pharmacodynamics**

No new pharmacodynamic data were submitted and none were required for applications of this type.

**IV.4 Clinical efficacy**

No new efficacy data were submitted and none were required for applications of this type.

**IV.5 Clinical safety**

No new safety data were submitted and none are required.

**IV.6 Risk Management Plan (RMP) and Pharmacovigilance System**

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 atorvastatin.
A summary of safety concerns and planned risk minimisation activities, as approved in the RMP, are listed below:

Summary table of safety concerns:

<table>
<thead>
<tr>
<th>Summary of safety concerns</th>
<th>Important identified risks</th>
<th>Important potential risks</th>
<th>Missing information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Hepatotoxicity</td>
<td>• Use during pregnancy</td>
<td>• Use in paediatrics &lt; 10 years of age</td>
</tr>
<tr>
<td></td>
<td>• Skeletal muscle effects, rhabdomyolysis and rhabdomyolysis-related events</td>
<td>• Use during breastfeeding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Haemorrhagic stroke</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Interstitial lung disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Diabetes mellitus</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Severe skin reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Interactions with CYP3A4 inhibitors and/or transport protein inhibitors</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Interactions with warfarin</td>
<td></td>
</tr>
</tbody>
</table>

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

IV.7 Discussion on the clinical aspects

With the exception of the bioequivalence study, 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.

Bioequivalence has been demonstrated between the applicant’s test product Atorvastatin 40 mg film-coated tablets (ELC Group s.r.o., Czech Republic) and the reference product Lipitor 40 mg film-coated tablets (Pfizer Ireland Pharmaceuticals).

As the 10 mg, 20 mg and 40 mg strength test products meet the biowaiver criteria specified in the current bioequivalence guidance, the results and conclusions of the bioequivalence study with the 40 mg tablet strength can be extrapolated to the 10 mg and 20 mg strength tablets.

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. The language used for the purpose of user testing the package leaflet 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 safety concerns have been identified. Extensive clinical experience with atorvastatin is considered to have demonstrated the therapeutic value of the compound. The benefit-risk 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 Atorvastatin is presented below:
PAR Atorvastatin 10 mg, 20 mg and 40 mg film-coated tablets

UK/H/5953/001-003/DC
PAR Atorvastatin 10 mg, 20 mg and 40 mg film-coated tablets

UK/H/5953/001-003/DC
PAR Atorvastatin 10 mg, 20 mg and 40 mg film-coated tablets

UK/H/5953/001-003/DC

Dimensions: 150 x 81 x 38 mm

Colours: 340C Black

Braille:

Atorvastatin 40 mg film-coated tablets

ELC GROUP

Atorvastatin 40 mg film-coated tablets

50 film-coated tablets

Oral use

Each film-coated tablet contains 40 mg atorvastatin (as atorvastatin calcium trihydrate). Each Atorvastatin 40 mg film-coated tablet contains 123.24 mg lactose monohydrate. See detailed information leaflet for further information.

Read the package leaflet before use. Oral use. Keep out of the sight and reach of children. Store below 25°C.
PAR Atorvastatin 10 mg, 20 mg and 40 mg film-coated tablets

Atorvastatin 40 mg
film-coated tablets

Oral use
100 film-coated tablets

Each film-coated tablet contains 40 mg atorvastatin as atorvastatin calcium.

Each Atorvastatin 40 mg film-coated tablet contains 103.24 mg microcrystalline cellulose.

See patient information leaflet for further information.

Mould the packaging leaflet before use.
Oral use.
Keep out of the sight and reach of children.
Store below 25°C.

Dimensions: 150 x 81 x 68 mm

Atorvastatin 40 mg
film-coated tablets