Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Atenolol 25mg Tablets (Atenolol)

PL 36722/0046

Special Concept Development (UK) Limited t/a Rx farma

LAY SUMMARY

Atenolol 25mg Tablets
Atenolol

This is a summary of the Public Assessment Report (PAR) for Atenolol 25mg Tablets. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

For practical information about using Atenolol 25mg Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Atenolol 25mg Tablets and what are they used for?
This application is the same as Atenolol 25mg Tablets (PL 39484/0010) which is already authorised.

The Company responsible for Atenolol 25mg Tablets has agreed that its scientific data can be used as the basis for the grant of an identical licence for Atenolol 25mg Tablets (PL 36722/0046).

Atenolol Tablets may be used for:
- high blood pressure
- relief of chest pain (angina)
- controlling heart beats which are irregular or too fast
- early treatment of myocardial infarction (heart attack)

How do Atenolol 25mg Tablets work?
Atenolol belongs to a group of medicines called beta blockers. It works by slowing the heart rate and relaxing the blood vessels so the heart does not have to pump as hard.

How are Atenolol 25mg Tablets used?
The pharmaceutical form of this medicine is a tablet and the route of administration is by mouth (oral).

Patients should follow these directions carefully, especially if the patient has been prescribed a low-salt or low-sodium diet.

Dosage – Treatment with Atenolol Tablets is usually long-term. Follow the doctor's advice on how and when to take the tablets. You should swallow the tablets whole with a glass of water. The dose you should take depends on what you are taking Atenolol Tablets for.

Adults:
- High blood pressure: The usual dose is 50mg – 100mg daily
- Angina: The usual dose 100mg once daily or 50mg twice daily
- Irregular heartbeats: The usual dose 50-100mg daily, given as a single dose
- Myocardial Infarction: Initial treatment will usually be by injection, followed by 50mg by mouth 15 minutes after the injection, a further 50mg 12 hours later and then 100mg 12 hours later to be given once daily.

Elderly: The dose will be similar to that of adults. The above dosages may sometimes be reduced especially if you have damaged kidneys.

Children: Not recommended.
Patients with kidney disease will usually be given a lower dose depending on how severe the kidney damage is. Patients on haemodialysis should be given 50mg by mouth after each dialysis.

For further information on how Atenolol 25mg Tablets are 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.
The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Atenolol 25mg Tablets have been shown in studies?
Atenolol 25mg Tablets are considered identical to the previously authorised product with the same benefits and risks. |No new studies have been provided for Atenolol 25mg Tablets, however, reference is made to the studies for Atenolol 25mg Tablets.

What are the possible side effects of Atenolol 25mg Tablets?
Atenolol 25mg Tablets are considered to be identical to the previously authorised product with the same benefits and risks.

For the full list of all side effects reported with this medicine, see Section 4 of the package leaflet or the Summary of Product Characteristics (SmPC) available on the MHRA website.

Why were Atenolol 25mg Tablets approved?
The MHRA decided that the benefits of Atenolol 25mg Tablets are greater than the risks and recommended that this medicine is approved for use.

What measures are being taken to ensure the safe and effective use of Atenolol 25mg Tablets?
A Risk Management Plan (RMP) has been developed to ensure that Atenolol 25mg Tablets is used as safely as possible. Based on this plan, safety information has been included in the SmPC and the package leaflet, 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 Atenolol 25mg Tablets
A Marketing Authorisation was granted in the UK on 20 January 2020.

The full PAR for Atenolol 25mg Tablets follows this summary.

This summary was last updated in March 2020.

TABLE OF CONTENTS

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Atenolol 25mg Tablets (PL 36722/0046) could be approved.

The product is approved for the following indications:

- Hypertension
- Angina pectoris
- Cardiac arrhythmias
- Acute myocardial infarction, as early intervention

Atenolol is a hydrophilic beta1-selective adrenoreceptor blocking drug, that is, it acts preferentially on beta1 -adrenoreceptors in the heart, but selectivity decreases with increasing dose. It does not have intrinsic sympathomimetic activity or membrane stabilising activity. Like other beta-adrenoceptor blocking drugs, its antihypertensive mode of action is unclear and it is negatively inotropic and so is contra-indicated in uncontrolled heart failure. Its reduction of heart rate and myocardial contractility is probably responsible for its anti-anginal activity. It is unlikely that the S- form has any therapeutic effects not possessed by the racemic mixture.

This is a national abridged application submitted under Article 10c of Directive 2001/83/EC, as amended an informed consent application. The application cross-refers to the reference product Atenolol 25mg Tablets (PL 39484/0010), currently held by Fourrts (UK) Pharmacare Limited.

No new non-clinical or clinical data have been supplied and none are required for this informed consent application.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the application is for an identical version of an already authorised product, no increase in environmental exposure is anticipated and no ERA is required.

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

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A Marketing Authorisation was granted on 20 January 2020.

II. EXPERT REPORT

The applicant cross-refers to the data for the reference product, to which this application is claimed to be identical. This is acceptable.

III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION SUMMARY OF PRODUCT CHARACTERITICS (SmPC)

The SmPC is in line with that of the reference product.

PATIENT INFORMATION LEAFLET
A leaflet mock-up has been provided which has been aligned with that for Atenolol 25mg Tablets (PL 39484/0010). The user test report submitted for PL 39484/0010 has been provided.

LABEL
Label mock-ups have been provided.

IV. QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specifications
The source of the active substance is in line with the cross-reference product. The proposed drug substance specification is consistent with the details registered for the cross-reference product.

IV.2. Drug Product

Name
The product has been named in line with current requirements.

Strength, pharmaceutical form, route of administration, container and pack sizes
Atenolol 25 mg Tablets are available in blister strips comprising aluminium foil on one side and PVC on the other. The strips are packed in cartons to contain 28 or 50 tablets.

The appearance of the product is identical to that of the cross-reference product.

The proposed shelf life of the product is 30 months with the storage conditions “Do not store above 25°C, Store in the original package”.

The proposed packaging, shelf life and storage conditions are consistent with the details registered for the reference product.

Legal status
Prescription only medicine (POM)

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

Qualitative and quantitative compositions
The composition of the proposed product is consistent with the details registered for the cross-reference product.

Manufacturing process & control of critical steps
The proposed manufacturing processes and process controls are consistent with the details registered for the reference product and the maximum batch size is stated.

Finished product release/shelf life specifications
The proposed finished product specifications are in line with the details registered for the cross-reference product.

TSE Compliance
No excipients of animal or human origin are used in the final products.

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

V. NON-CLINICAL ASPECTS
As this application is submitted under Article 10c of Directive 2001/83/EC, as amended, (as an informed consent application) no new non-clinical data have been supplied and none are required.

VI. CLINICAL ASPECTS
As this application is submitted under Article 10c of Directive 2001/83/EC, as amended, (as an informed consent application) no new clinical data have been supplied and none are required.

VII. RISK MANAGEMENT PLAN (RMP)
The applicant has submitted an RMP, in accordance with the requirements of Directive 2001/83/EC, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

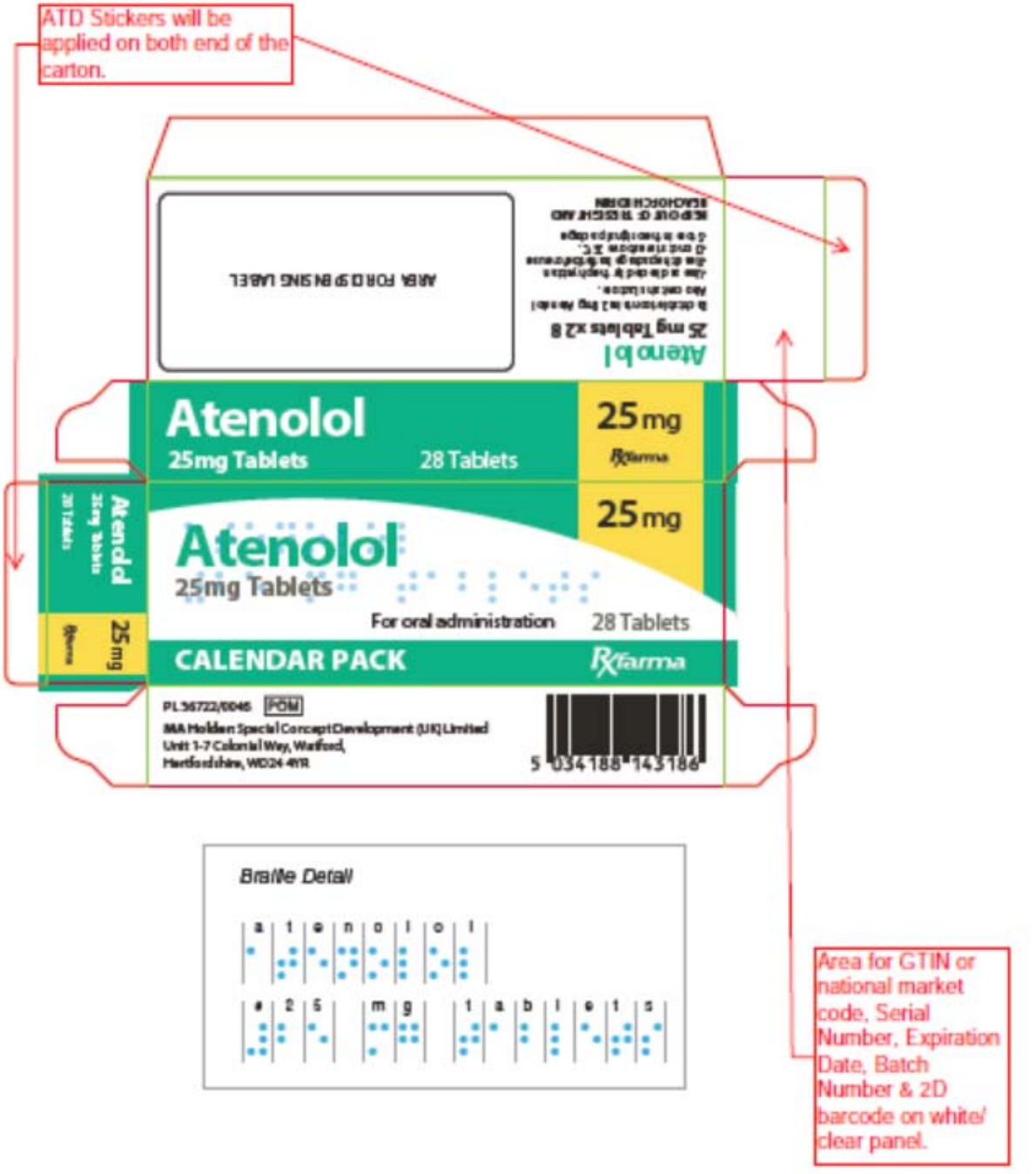
VIII. USER CONSULTATION
The Patient Information Leaflet (PIL) has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The results show that the PIL meets the criteria for readability as set out in the guideline on the readability of the label and package leaflet of medicinal products for human use.

IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION
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 the cross-reference product. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference product and positive.

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the cross-reference product.

In accordance with Directive 2012/84/EU, the current approved UK versions of the SmPCs and PILs for these products are available on the MHRA website.

Representative copies of the labels at the time of UK licensing are provided below.


ATD Stickers will be applied on both end of the carton.
Atenolol
25mg Tablets
28 Tablets
25mg
Rxfarma
Atenolol
25mg Tablets
For oral administration
28 Tablets
CALENDAR PACK
Rxfarma
PL 36722/0046
POM
MA Holden Special Concept Development (UK) Limited
Unit 1-7 Colonial Way, Watford,
Hertfordshire, WD24 4YR
5 034188 143186
Braille Detail
a t e n o l o l
2 5 m g t a b l e t s
Area for GTIN or national market code, Serial Number, Expiration Date, Batch Number & 2D barcode on white/ clear panel.

#

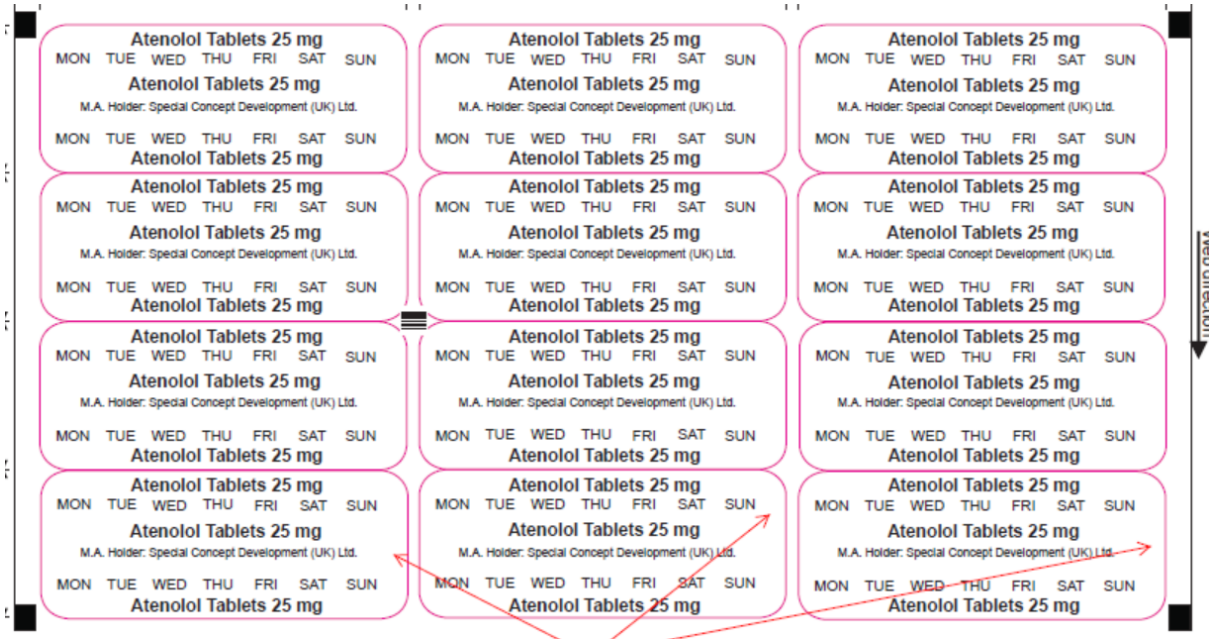


TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**