Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Atenolol 25 mg film-coated tablets
Atenolol 50 mg film-coated tablets
Atenolol 100 mg film-coated tablets

atenolol

PL 43252/0058 - 0060

ATNAHS PHARMA UK LIMITED

LAY SUMMARY

Atenolol 25 mg, 50 mg and 100 mg film-coated tablets
atenolol

This is a summary of the Public Assessment Report (PAR) for Atenolol 25 mg, 50 mg and 100 mg film-coated tablets. It explains how these products 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 Atenolol 25 mg, 50 mg and 100 mg film-coated tablets, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Atenolol 25 mg, 50 mg and 100 mg film-coated tablets and what are it/they used for?
These applications are the same as Tenormin 25 mg, LS 50 mg and 100 mg tablets (PL 43252/0038 - 0040) which are already authorised.

The application is presented by the same Applicant as the MAH of the cross-reference product. The Company requested that its scientific data be used as the basis for the grant of an identical licences for Atenolol 25 mg, 50 mg and 100 mg film-coated tablets.

Atenolol 25 mg, 50 mg and 100 mg film-coated tablets are used to:

- Treat high blood pressure (hypertension)
- Treat uneven heart beats (arrhythmias)
- Help prevent chest pain (angina)
- Protect the heart in the early treatment after a heart attack (myocardial infarction).

How do Atenolol 25 mg, 50 mg and 100 mg film-coated tablets work?
Atenolol film-coated tablets contains a medicine called atenolol. This belongs to a group of medicines called beta-blockers. It works by making the heart beat more slowly and with less force.

How are Atenolol 25 mg, 50 mg and 100 mg film-coated tablets used?
The pharmaceutical form of these medicines is film-coated tablets and the route of administration is oral (by mouth). Patients should swallow these tablets whole with a drink of water and try to take the medicine at the same time each day.

The patient's doctor will tell them how many tablets to take each day and when to take them. Patients should read the label on the carton for a reminder of what the doctor said.

<u>Adults</u>

- High blood pressure (hypertension): the recommended dose is 50 mg to 100 mg a day.
- Chest pain (angina): the recommended dose is 100 mg a day or 50 mg twice a day.
- Uneven heart beats (arrhythmias): the recommended dose is 50 mg to 100 mg a day.
- The early treatment of a heart attack (myocardial infarction): the recommended dose is 50 mg to 100 mg a day.

<u>Elderly</u>
The patient's doctor may decide to give them a lower dose, particularly if the patient has problems with their kidneys.

People with severe kidney problems
If the patient has severe kidney problems, their doctor may decide to give them a lower dose.

Use in Children
This medicine must not be given to children

For further information on how Atenolol 25 mg, 50 mg and 100 mg film-coated tablets are used, refer to the PIL and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicines 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 25 mg, 50 mg and 100 mg film-coated tablets have been shown in studies?
Atenolol 25 mg, 50 mg and 100 mg film-coated tablets are considered identical to the previously authorised product/products with the same benefits and risks. No new studies have been provided for Atenolol 25 mg, 50 mg and 100 mg film-coated tablets, however, reference is made to the studies for Tenormin 25 mg, LS 50 mg and 100 mg tablets.

What are the possible side effects of Atenolol 25 mg, 50 mg and 100 mg film-coated tablets?
For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPCs available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Atenolol 25 mg, 50 mg and 100 mg film-coated tablets are considered to be identical to the previously authorised product/products with the same benefits and risks.

Why were Atenolol 25 mg, 50 mg and 100 mg film-coated tablets approved?
The MHRA decided that the benefits of Atenolol 25 mg, 50 mg and 100 mg film-coated tablets are greater than the risks and recommended that these medicines are approved for use.

What measures are being taken to ensure the safe and effective use of Atenolol 25 mg, 50 mg and 100 mg film-coated tablets?
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Atenolol 25 mg, 50 mg and 100 mg film-coated tablets The RMP details the important risks of Atenolol 25 mg, 50 mg and 100 mg film-coated tablets, how these risks can be minimised, any uncertainties about Atenolol 25 mg, 50 mg and 100 mg film-coated tablets (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Atenolol 25 mg, 50 mg and 100 mg film-coated tablets.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Atenolol 25 mg, 50 mg and 100 mg film-coated tablets are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Other information about Atenolol 25 mg, 50 mg and 100 mg film-coated tablets
Marketing Authorisations were granted in the UK on 02 May 2025.

The full PAR for Atenolol 25 mg, 50 mg and 100 mg film-coated tablets follows this summary.

This summary was last updated in June 2025.

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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 applications for Atenolol 25 mg, 50 mg and 100 mg film-coated tablets (PL 43252/0058 - 0060) could be approved.

The products are approved for the following indications:

- Management of hypertension.
- Management of angina pectoris.
- Management of cardiac arrhythmias.
- Management of myocardial infarction. Early intervention in the acute phase.

Atenolol is a beta-blocker which is beta1-selective, (i.e. acts preferentially on beta1- adrenergic receptors in the heart). Selectivity decreases with increasing dose.

Atenolol is without intrinsic sympathomimetic and membrane-stabilising activities and as with other beta-blockers, has negative inotropic effects (and is therefore contraindicated in uncontrolled heart failure).

As with other beta-blockers, the mode of action of atenolol in the treatment of hypertension is unclear. It is probably the action of atenolol in reducing cardiac rate and contractility which makes it effective in eliminating or reducing the symptoms of patients with angina. It is unlikely that any additional ancillary properties possessed by S (-) atenolol, in comparison with the racemic mixture, will give rise to different therapeutic effects.

These are national abridged applications approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as informed consent applications. The applications cross-refer to the reference products Tenormin 25 mg, LS 50 mg and 100 mg tablets.

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

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the applications are for identical versions of already authorised products, 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 these products at all sites responsible for the manufacture, assembly and batch release of these products.

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

National marketing authorisations were granted in the UK on 2 May 2025.

II. EXPERT REPORT

The applicant cross-refers to the data for Tenormin 25 mg, LS 50mg and 100mg tablets (PL 43252/0038 - 0040; Atnahs Pharma UK Limited) to which these applications are claimed to be identical. This is acceptable.

III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION

Summaries of Product Characteristics (SmPCs)
The SmPCs are in line with those for the cross-reference products, dated 01/09/2021.

PATIENT INFORMATION LEAFLET
Leaflet text was provided which has been aligned with that for the cross-reference products dated for 03/2023. Atnahs Pharma UK Limited requested a waiver from user testing and this request was considered acceptable, as there are no changes to previously user-tested leaflets and product information assessed by the MHRA.

LABEL
Label text has been provided.

IV. QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specification(s)
The source(s) of the active substance(s) are in line with the cross-reference products. The proposed drug substance specification is consistent with the details registered for the cross-reference products.

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, 50 mg and 100 mg film-coated tablets are available in the following:

- Atenolol 25 mg film-coated tablets - Aluminium PVC/PVDC blister strips of 28 tablets.
- Atenolol 50 mg and 100 mg film-coated tablets - Aluminium PVC blister strips of 14 tablets in cartons of 28 Tablets or Aluminium PVC blister strips of 7 tablets in cartons of 504 Tablets (for Hospital Use; pack is subdivided into 6 cartons each containing 12 blister strips i.e. 84 tablets)

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

The proposed shelf life of the product is 60 months with the recommended storage conditions 'Do not store above 25°C. Store in the original package. Keep the container in the outer carton'.

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 site(s) are consistent with the details registered for the cross-reference products and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

Qualitative and quantitative compositions
The composition of the proposed products are consistent with the details registered for the

cross-reference products.

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

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

TSE Compliance
With the exception of gelatin no excipients of animal or human origin are used in the final products. Copies of the current TSE certificates for suppliers of gelatin have been provided and are current in accordance with EDQM database.

Confirmation has been given that the magnesium stearate used in the tablets is of vegetable origin.

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

V. NON-CLINICAL ASPECTS
As these applications are submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as informed consent applications) no new non-clinical data have been supplied and none are required.

VI. CLINICAL ASPECTS
As these applications are submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as informed consent applications) 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 Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VIII. USER CONSULTATION
Text drafts of the Patient Information Leaflet (PIL) were presented. Atnahs Pharma UK Limited requested a waiver from user testing and this request was considered acceptable.

IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s products are identical to the cross-reference products. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference products and positive.

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

In accordance with legal requirements, the current approved UK versions of the SmPCs and PILs for these products are available on the MHRA website.

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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**