



# **Public Assessment Report**

## **National Procedure**

**Amlodipine 5 mg Tablets**  
**Amlodipine 10 mg Tablets**

**amlodipine besilate**

**PL 00289/2668 - 2669**

**TEVA UK LIMITED**

## LAY SUMMARY

### Amlodipine 5 mg and 10 mg Tablets

#### amlodipine besilate

This is a summary of the Public Assessment Report (PAR) for Amlodipine 5 mg and 10 mg 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.

These products will be referred to as Amlodipine Tablets in this lay summary for ease of reading.

These applications were approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the EU/EEA (RMS: Netherlands), with the procedure number NL/H/5921/001-002/DC. The procedure followed route A.

These applications were approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended).

These products are generic medicines. This means that these medicines are the same as, and considered interchangeable with, reference medicines already authorised, called Istin 5 mg and 10 mg Tablets (PL 50622/0033 and PL 50622/0031).

For practical information about using Amlodipine Tablets, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

#### **What are Amlodipine Tablets and what are they used for?**

Amlodipine Tablets contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists. Amlodipine is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina.

#### **How do Amlodipine Tablets work?**

In patients with high blood pressure this medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina Amlodipine works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. This medicine does not provide immediate relief of chest pain from angina.

#### **How are Amlodipine Tablets used?**

The pharmaceutical form of these medicines is tablet and the route of administration is oral (by mouth). This medicine can be used before or after food and drinks. Patients should take this medicine at the same time each day with a drink of water. Do not take Amlodipine with grapefruit juice.

The recommended initial dose is Amlodipine 5 mg once daily. The dose can be increased to Amlodipine 10 mg once daily.

For children and adolescents (6-17 years old), the recommended usual starting dose is 2.5 mg a day. The maximum recommended dose is 5 mg a day. Amlodipine 5 mg tablets can be divided

into halves to provide a 2.5 mg dose. It is important to keep taking the tablets. Patient's should not wait until the tablets are finished before seeing their doctor.

For further information on how Amlodipine 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 Amlodipine Tablets have been shown in studies?**

Because Amlodipine Tablets are generic medicines, studies in healthy volunteers have been limited to tests to determine that they are bioequivalent to the reference medicines. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

### **What are the possible side effects of Amlodipine 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.

Because Amlodipine Tablets are generic medicines and are bioequivalent to the reference medicines, their benefits and possible side effects are considered to be the same as the reference medicines.

### **Why were Amlodipine Tablets approved?**

It was concluded that, Amlodipine Tablets has been shown to be bioequivalent to the reference medicine. Therefore, the MHRA decided that, as for the reference medicine, the benefits are greater than the risks and recommended that it can be approved for use.

### **What measures are being taken to ensure the safe and effective use of Amlodipine Tablets?**

As for all newly-authorized medicines, a Risk Management Plan (RMP) has been developed for Amlodipine Tablets. The RMP details the important risks of Amlodipine Tablets, how these risks can be minimised, any uncertainties about Amlodipine 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 Amlodipine 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 Amlodipine 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 Amlodipine Tablets**

Marketing authorisations were granted in the United Kingdom on 16 January 2026.

The full PAR for Amlodipine Tablets follows this summary.

This summary was last updated in February 2026.

## TABLE OF CONTENTS

<b>I.</b>	<b>INTRODUCTION</b> .....	6
<b>II.</b>	<b>PRODUCT INFORMATION</b> .....	6
<b>III.</b>	<b>QUALITY ASPECTS</b> .....	7
<b>IV.</b>	<b>NON-CLINICAL ASPECTS</b> .....	7
<b>V.</b>	<b>CLINICAL ASPECTS</b> .....	7
<b>VI.</b>	<b>RISK MANAGEMENT PLAN (RMP)</b> .....	7
<b>VII.</b>	<b>USER CONSULTATION</b> .....	7
<b>VIII.</b>	<b>OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION</b> .....	7
	<b>TABLE OF CONTENT OF THE PAR UPDATE</b> .....	8

## 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 Amlodipine 5 mg and 10 mg Tablets (PL 00289/2668 - 2669) could be approved.

The products are approved for the following indications:

- Hypertension
- Chronic stable angina pectoris
- Vasospastic (Prinzmetal's) angina.

The active substance in these products is amlodipine besilate.

Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle.

The mechanism of the antihypertensive action of amlodipine is due to a direct relaxant effect on vascular smooth muscle. The precise mechanism by which amlodipine relieves angina has not been fully determined but amlodipine reduces total ischaemic burden by the following two actions:

- 1) Amlodipine dilates peripheral arterioles and thus, reduces the total peripheral resistance (afterload) against which the heart works. Since the heart rate remains stable, this unloading of the heart reduces myocardial energy consumption and oxygen requirements.
- 2) The mechanism of action of amlodipine also probably involves dilatation of the main coronary arteries and coronary arterioles, both in normal and ischaemic regions. This dilatation increases myocardial oxygen delivery in patients with coronary artery spasm (Prinzmetal's or variant angina).

These applications were approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the EU/EEA (RMS: Netherlands), with the procedure number NL/H/5921/001-002/DC. For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the reference regulator, please refer to the public assessment report on the relevant competent authority's website.

These applications were approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended).

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.

Marketing authorisations were granted on 16 January 2026.

## II. PRODUCT INFORMATION

### Summaries of Product Characteristics (SmPCs)

The SmPCs are in line with current guidelines and are satisfactory.

**PATIENT INFORMATION LEAFLET (PIL)**

The PIL is in line with current guidelines and is satisfactory.

**LABEL**

The labelling is in line with current guidelines and is satisfactory.

**III. QUALITY ASPECTS**

MHRA considered that the quality data submitted for these applications are satisfactory. The grant of marketing authorisations was recommended.

**IV. NON-CLINICAL ASPECTS**

Pharmacodynamic, pharmacokinetic and toxicological properties of amlodipine are well known. As amlodipine is a widely used, well-known active substance, the applicant has not provided additional studies and further studies are not required. Overview based on literature review is, thus, appropriate.

MHRA considered that the non-clinical data submitted for these applications are satisfactory. The grant of marketing authorisations was recommended.

**V. CLINICAL ASPECTS**

MHRA considered that the clinical data submitted for these applications are satisfactory. The grant of marketing authorisations was recommended.

**VI. 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.

**VII. USER CONSULTATION**

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

**VIII. 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 benefit/risk balance is, therefore, considered to be positive.

The Summaries of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and labelling are satisfactory.

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

**IX. 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 SmPCs and/or PIL available on the MHRA website.

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