IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

Amlodipine Upjohn 10 mg tablets
Amlodipine
PA23055/013/002

The Public Assessment Report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation for a specific medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the medicinal product for marketing in Ireland.

CONTENTS

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for Amlodipine Pfizer 5 mg & 10 mg tablets, from Pfizer Limited. on 9th December 2011 for the management of essential hypertension.

This application for a marketing authorisation was submitted in accordance with Article 10c of Directive 2001/83/EC and is referred to as a duplicate application. This means that the Marketing Authorisation Holder for Istin 5 mg & 10 mg Tablet, authorised medicinal products in Europe, has referred to their dossier to obtain an authorisation for Amlodipine Pfizer 5 mg & 10 mg tablets. Amlodipine Pfizer 5 mg & 10 mg tablets have the same qualitative and quantitative composition in terms of actives substances and the same pharmaceutical form as Istin 5 mg & 10 mg Tablets.

The products are subject to a renewable prescription.

The Summary of Product Characteristics for (SPC) for this medicinal product is available on the HPRA 's website at http://www.HPRA.ie/

Name of the product	Amlodipine Pfizer 5 mg tablets & Amlodipine Pfizer 10 mg tablets
Name(s) of the active substance(s) (INN)	AMLODIPINE BESILATE
Pharmacotherapeutic classification (ATC code)	C08CA 01
Pharmaceutical form and strength(s)	5 mg & 10 mg
Marketing Authorisation Number(s) in Ireland (PA)	PA 0822/210/001-002
Marketing Authorisation Holder	Pfizer Limited

II. QUALITY ASPECTS

II.1. – II.3. Introduction

This application is for Amlodipine Pfizer 5 mg tablets and Amlodipine Pfizer 10 mg tablets.

Since this application is a duplicate of the Pfizer limited Istin application, the Quality data in support of this product are identical to the up-to-date Quality data of the Istin dossier which has been assessed and approved. More detailed Quality comment is not pertinent.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Amlodipine Pfizer 5 mg tablets and Amlodipine Pfizer 10 mg tablets.

III. NON-CLINICAL ASPECTS

III.1 Introduction

This active substance has been available on the European/Irish market for more than ten years. Preclinical data have been superseded by clinical experience and therefore no preclinical assessment report is available.

IV. CLINICAL ASPECTS

IV.1 Introduction

Amlodipine Pfizer 5 mg tablets & Amlodipine Pfizer 10 mg tablets are well known active substance with established efficacy and tolerability. The content of the SPCs approved during the national procedure is in accordance with those accepted for the reference product Istin.

IV.5 Clinical Safety

The Marketing Authorisation Holder submitted a set of documents describing the Pharmacovigilance System, including information on the availability of an EU Qualified Person for Pharmacovigilance (EU-QPPV) and the means for notification of adverse reaction reports in the EU or from a Third Country.

IV.6 Discussion on the clinical aspects

The application for product authorisations for Amlodipine Pfizer 5 mg tablets & Amlodipine Pfizer 10 mg tablets based on the principle of informed consent i.e. it is a duplicate of the Istin application. The clinical data in support of these products are identical to the clinical data in the Istin dossier which has been assessed and approved.

V. OVERALL CONCLUSIONS

BENEFIT/RISK ASSESSMENT AND RECOMENDATION
Amlodipine Pfizer 5 mg tablets and Amlodipine Pfizer 10 mg tabletsare the same as Istin 5 mg & Istin 10 mg tablets. As Istin 5mg & 10mg tablets are well-known medicinal products with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile, the quality of Amlodipine Pfizer 5mg tablets and Amlodipine Pfizer 10 mg tablets are established to be equally acceptable.
The MAH has provided written confirmation that systems and services are in place to ensure compliance with their pharmacovigilance obligations.

The HPRA, on the basis of the data submitted considered that Amlodipine Pfizer 5 mg & 10 mg tablets were duplicates of Istin 5 mg & 10 mg and therefore granted marketing authorisations (PA 0019/055/001-002).

VI. REVISION DATE

November 2021

VII. UPDATES

SCOPE	PROCEDURE NUMBER	PRODUCT INFORMATION AFFECTED	DATE OF START OF PROCEDURE	DATE OF END OF PROCEDURE
MAH transfer	CRN00C1RW	SmPC section 7, 8, 10 Package Leaflet New MA Holder: Upjohn EESV New PA number: PA23055/013/001-002	N/A	12/11/2021