COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Nevirapine Sandoz 200 mg tablets

(nevirapine)

NL/H/5154/001/DC

Date: 30 April 2020

This module reflects the scientific discussion for the approval of Nevirapine Sandoz 200 mg tablets. The procedure was finalised at 27 July 2012. For information on changes after this date please refer to the 'steps taken after finalisation' at the end of this PAR.

List of abbreviations

CEP	Certificate of Suitability to the monographs of the European Pharmacopoeia
CMD(h)	Coordination group for Mutual recognition and Decentralised procedure for human medicinal products
CMS	Concerned Member State
EEA	European Economic Area
ERA	Environmental Risk Assessment
ICH	International Conference of Harmonisation
MAH	Marketing Authorisation Holder
Ph.Eur.	European Pharmacopoeia
PL	Package Leaflet
RH	Relative Humidity
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have granted a marketing authorisation for Nevirapine Sandoz 200 mg tablets from Sandoz B.V.

The product is indicated in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infected adults, adolescents, and children of any age.

A comprehensive description of the indications and posology is given in the SmPC.

This decentralised procedure concerns a generic application claiming essential similarity with the innovator product Viramune 200 mg tablets (EU/1/97/055) which has been registered in the EEA by Boehringer Ingelheim International GmbH since 4 February 1998.

The concerned member states (CMS) involved in this procedure were Austria, Belgium, Germany, Spain, Italy, Luxembourg, Malta, Romania, and the United Kingdom.

The marketing authorisation has been granted pursuant to Article 10(1) of Directive 2001/83/EC.

II. QUALITY ASPECTS

II.1 Introduction

Nevirapine Sandoz 200 mg tablets, contain nevirapine as the active substance.

The tablets are packed in PVC-Aluminium blisters.

The excipients are microcrystalline cellulose, maize starch, croscarmellose sodium, povidone (K30), silica colloidal anhydrous, sodium starch glycolate, magnesium stearate.

II.2 Drug Substance

The chemical-pharmaceutical documentation and expert report in relation to nevirapine are of sufficient quality in view of the present European regulatory requirements.
The manufacturer of the drug substance has obtained a Certificate of Suitability.
The drug substance specifications and analytical methods comply with the Ph.Eur. monograph.

II.3 Medicinal Product

The drug product has been manufactured using the conventional pharmaceutical excipients and with the standard manufacturing process.
The development of the product has been described, the choice of excipients is justified and their functions explained.
The results obtained up-to-date in the stability studies conducted with the finished product show that the formula and manufacturing process established lead to a product with appropriate quality profile.

II.4 Discussion on chemical, pharmaceutical and biological aspects

Based on the submitted dossier, the member states consider that Nevirapine Sandoz has a proven chemical-pharmaceutical quality. Sufficient controls have been laid down for the active substance and finished product.

No post-approval commitments were made.

III. NON-CLINICAL ASPECTS

III.1 Ecotoxicity/environmental risk assessment (ERA)

Since Nevirapine Sandoz 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.2 Discussion on the non-clinical aspects

This product is a generic formulation of Viramune which is available on the European market. Reference is made to the preclinical data obtained with the innovator product. A non-clinical overview on the pharmacology, pharmacokinetics and toxicology has been provided, which is based on up-to-date and adequate scientific literature. The overview justifies why there is no need to generate additional non-clinical pharmacology, pharmacokinetics and toxicology data. Therefore, the member states agreed that no further non-clinical studies are required.

IV. CLINICAL ASPECTS

For this authorisation, reference is made to the clinical studies and experience with the innovator product Viramune. No new clinical studies were conducted. The MAH demonstrated through a bioequivalence study that the pharmacokinetic profile of the product is similar to the pharmacokinetic profile of this reference product. Risk management

is adequately addressed. This generic medicinal product can be used instead of the reference product.

V. USER CONSULTATION

The readability of the package leaflet was successfully demonstrated.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Nevirapine Sandoz 200 mg tablets has a proven chemical-pharmaceutical quality and is a generic form of Viramune 200 mg tablets. Viramune is a well-known medicinal product with an established favourable efficacy and safety profile.

Bioequivalence has been shown to be in compliance with the requirements of European guidance documents.

The Board followed the advice of the assessors.

There was no discussion in the CMD(h). Agreement between member states was reached during a written procedure. The member states, on the basis of the data submitted, considered that essential similarity has been demonstrated for Nevirapine Sandoz with the reference product, and have therefore granted a marketing authorisation. The decentralised procedure was finalised with a positive outcome on 27 July 2012.