LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Nevirapine Medical Valley
nevirapine (anhydrous)

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This module reflects the scientific discussion for the approval of Nevirapine Medical Valley. The Summary Public Assessment Report was written in September 2017 by the previous RMS (NL) after initial procedure NL/H/3541/001/DC. RMS transfer from NL to SE was completed 2021-09-22.

Nevirapine Medical Valley

nevirapine (anhydrous)

Prolonged-release tablet, 400 mg

This is a summary of the public assessment report (PAR) for Nevirapine Medical Valley. It explains how Nevirapine Medical Valley 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 Nevirapine Medical Valley.

For practical information about using Nevirapine Medical Valley, patients should read the package leaflet or contact their doctor or pharmacist.

The summary of the public assessment report was written in September 2017 by the previous RMS NL after the initial procedure NL/H/3541/001/DC and is attached at the end of this document.

Public Assessment Report – Update

Procedure number*	Scope	Product Information affected (Yes/No)	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse

*Only procedure qualifier, chronological number and grouping qualifier (when applicable)

Summary Public Assessment Report

Generics

Nevirapine Hetero Europe 400 mg prolonged release tablets

(nevirapine)

NL/H/3541/001/DC

Date: 5 September 2017

Summary Public Assessment Report

Generics

Nevirapine Hetero Europe 400 mg prolonged release tablets

Active substance: nevirapine

This is a summary of the public assessment report (PAR) for Nevirapine Hetero Europe 400 mg prolonged release tablets. It explains how this medicine 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 Nevirapine Hetero Europe.

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Nevirapine Hetero Europe and what is it used for?
Nevirapine Hetero Europe is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Viramune 400 mg prolonged release tablets.

Nevirapine Hetero Europe is used in combination with other antiviral medicines to treat patients infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

How does this medicine work?
Nevirapine Hetero Europe is an antiviral medicine. The active substance in Nevirapine Hetero Europe, nevirapine, is a non-nucleoside reverse-transcriptase inhibitor (NNRTI). It blocks the activity of reverse transcriptase, an enzyme produced by HIV-1 that allows it to infect cells in the body and make more viruses. By blocking this enzyme, Nevirapine Hetero Europe, taken in combination with other antiviral medicines, reduces the amount of

HIV-1 in the blood and keeps it at a low level. Nevirapine Hetero Europe does not cure HIV-1 infection or AIDS, but it may delay the damage to the immune system and the development of infections and diseases associated with AIDS.

How is this medicine used?
The pharmaceutical form of Nevirapine Hetero Europe is a prolonged release tablet and the route of administration is oral.
The medicine can only be obtained with a prescription. The prolonged-release tablets are recommended to be taken with liquid, and should not be broken or chewed. Nevirapine Hetero Europe can be used with or without food.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
Because Nevirapine Hetero Europe is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Viramune. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of this medicine?
Because Nevirapine Hetero Europe is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Viramune, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Nevirapine Hetero Europe, 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/reviewed continuously as well.

Other information about this medicine
In the Netherlands, the marketing authorisation for Nevirapine Hetero Europe 400 mg prolonged release tablets was granted on 10 July 2017.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Nevirapine Hetero Europe, read the package leaflet (https://db.cbg-meb.nl/Bijsluiters/h117663_piluk.pdf) or contact your doctor or pharmacist.

This summary was last updated in September 2017.