COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark 600 mg/200 mg/245 mg film-coated tablets

(efavirenz, emtricitabine and tenofovir disoproxil)

NL/H/4283/001/DC

Date: 28 August 2019

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Active substances: efavirenz, emtricitabine and tenofovir disoproxil

This is a summary of the public assessment report (PAR) for Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark. 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 Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark.

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

What is Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark and what is it used for?
Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Atripla 600 mg/200 mg/245 mg film-coated tablets.

Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark is a treatment for Human Immunodeficiency Virus (HIV) infection in adults aged 18 years and over who have previously been treated with other antiretroviral medicines and have their HIV-1 infection under control for at least three months. Patients must not have experienced failure of a previous HIV therapy.

How does this medicine work?
Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark contains three active substances that are used to treat HIV infection:

- Efavirenz is a non-nucleoside reverse transcriptase inhibitor (NNRTI)
- Emtricitabine is a nucleoside reverse transcriptase inhibitor (NRTI)
- Tenofovir is a nucleotide reverse transcriptase inhibitor (NtRTI)

Each of these active substances, also known as antiretroviral medicines, work by interfering with an enzyme (reverse transcriptase) that is essential for the virus to multiply.

How is this medicine used?
The pharmaceutical form of Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark is a film-coated tablet and the route of administration is oral. The tablet should be swallowed whole with water on a empty stomach, preferably at bedtime.

The medicine can only be obtained with a prescription.

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 Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Atripla. 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 Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark 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 Atripla, 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 Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark, 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 Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark was granted on 23 May 2019.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Efavirenz/Emtricitabine/Tenofovir disoproxil Glenmark, read the package leaflet (https://mri.cts-mrp.eu/Human/Downloads/NL_H_4283_001_FinalPI.pdf) or contact your doctor or pharmacist.

This summary was last updated in August 2019.