LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Emtenef
(emtricitabine, tenofovir disoproxil succinate, tenofovir disoproxil, efavirenz)

SE/H/2467/001/DC

This module reflects the scientific discussion for the approval of Emtenef. The Summary Public Assessment Report was written in 26 October 2017 by the previous RMS (NL) after initial procedure <NL/H/3892/001/DC>. RMS transfer from (NL) to SE was completed 24 June 2023.

Active substance	efavirenz emtricitabine tenofovir disoproxil succinate tenofovir disoproxil
Pharmaceutical form	Film-coated tablet
Strength	600 mg/200 mg/245 mg
Applicant	STADA Arzneimittel AG
EU-Procedure number (original)	(NL/H/3892/001/DC)

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Generics

Emtenef 600 mg/200 mg/245 mg, film-coated tablets

(efavirenz, emtricitabine and tenofovir disoproxil)

NL/H/3892/001/DC

Date: 26 October 2017

Summary Public Assessment Report

Emtenef 600 mg/200 mg/245 mg, film-coated tablets

Active substances: efavirenz, emtricitabine and tenofovir disoproxil

This is a summary of the public assessment report (PAR) for Emtenef. 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 Emtenef.

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

What is Emtenef and what is it used for?
Emtenef 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.

Emtenef 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?
Emtenef 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 Emtenef 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 Emtenef 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 Emtenef 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 Emtenef, 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.

Additional risk minimisation measures are required relating to the safe and effective use of this medicine. These have been laid down in line with the reference product. It concerns a educational pack for physician who are expected to prescribe Emtenef containing the Summary of Product Characteristics and a HIV renal educational brochure.

Other information about this medicine
In the Netherlands, the marketing authorisation for Emtenef 600 mg/200 mg/245 mg, film-coated tablets was granted on 25 September 2017.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Emtenef, read the package leaflet (https://mri.cts-mrp.eu/Human/Downloads/NL_H_3892_001_FinalPI.pdf) or contact your doctor or pharmacist. This summary was last updated in October 2017.