

Summary Public Assessment Report

Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s. (tenofovir disoproxil fumarate, efavirenz, emtricitabine)

SE/H/2158/01/DC

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Film-coated tablet, 600 mg/200 mg/245 mg

This is a summary of the public assessment report (PAR) for Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s.. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s. and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Atripla.

The product 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 Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s. work?

It contains three active substances that are used to treat human immunodeficiency virus (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 Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s. used?

The pharmaceutical form is film-coated tablet for oral use.

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

The medicine can only be obtained with a prescription in Sweden.

What benefits of Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s. have been shown in studies?

Because the product is a generic medicine, studies 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 from Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s.?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of restrictions, see the package leaflet.

Why is Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s. approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Atripla, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s.?

A risk management plan has been developed to ensure that the product 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, 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. For more details, please see the full PAR for Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s. on the following website: [MRI - Home](#).

Other information about Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s.

The full PAR for Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s. can be found on the following website: [MRI - Home](#). For more information about treatment with Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva k.s., please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-06.