LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Tenofovir disoproxil Teva (tenofovir disoproxil)

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Summary Public Assessment Report

Tenofovir disoproxil Teva

(tenofovir disoproxil)

film-coated tablet, 245 mg

This is a summary of the public assessment report (PAR) for Tenofovir disoproxil Teva. It explains how Tenofovir disoproxil Teva 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 Tenofovir disoproxil Teva.

For practical information about using Tenofovir disoproxil Teva, patients should read the package leaflet or contact their doctor or pharmacist.

What is Tenofovir disoproxil Teva and what is it used for?

Tenofovir disoproxil Teva is a 'generic medicine'. This means that Tenofovir disoproxil Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Viread.
Tenofovir disoproxil Teva is used in the treatment of HIV (Human Immunodeficiency Virus) infection and chronic hepatitis B, an infection with HBV (hepatitis B virus).

How does Tenofovir disoproxil Teva work?

Tenofovir disoproxil Teva contains the active substance tenofovir disoproxil. This active substance is an antiretroviral or antiviral medicine which is used to treat HIV or HBV infection or both. Tenofovir is a nucleotide reverse transcriptase inhibitor, generally known as an NRTI and works by interfering with the normal working of enzymes (in HIV reverse transcriptase; in hepatitis B DNA polymerase) that are essential for the viruses to reproduce themselves. In HIV Tenofovir Disoproxil Teva should always be used combined with other medicines to treat HIV infection.

How is Tenofovir disoproxil Teva used?

The pharmaceutical form of Tenofovir disoproxil Teva 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.

What benefits of Tenofovir disoproxil Teva have been shown in studies?

Because Tenofovir disoproxil Teva is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Viread. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Tenofovir disoproxil Teva?

Because Tenofovir disoproxil Teva 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 restrictions, see the package leaflet.

Why is Tenofovir disoproxil Teva approved?

It was concluded that, in accordance with EU requirements, Tenofovir disoproxil Teva has been shown to have comparable quality and to be bioequivalent to the reference medicine Viread. Therefore, the Medical Products Agency in Sweden decided that, as for Viread, 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 Tenofovir disoproxil Teva?

A risk management plan has been developed to ensure that Tenofovir disoproxil Teva 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 Tenofovir disoproxil Teva, 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 Tenofovir disoproxil Teva

The marketing authorisation for Tenofovir disoproxil Teva was granted on 2015-09-10 in Sweden.

The full PAR for Tenofovir disoproxil Teva can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Tenofovir disoproxil Teva, please read the [package leaflet] or contact your doctor or pharmacist.

This summary was last updated in 2015-09-10.