EMA/9058/2018
EMEA/H/C/004274

EPAR summary for the public

Efavirenz/Emtricitabine/Tenofovir disoproxil Krka

efavirenz / emtricitabine / tenofovir disoproxil

This is a summary of the European public assessment report (EPAR) for Efavirenz/Emtricitabine/Tenofovir disoproxil Krka. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use the medicine.

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

What is Efavirenz/Emtricitabine/Tenofovir disoproxil Krka and what is it used for?

Efavirenz/Emtricitabine/Tenofovir disoproxil Krka is an antiviral medicine used to treat adults infected with human immunodeficiency virus-1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

It is only used in patients whose levels of HIV in the blood (viral load) have been below 50 copies/ml for more than 3 months on their current HIV treatment combination. It must not be used in patients in whom any previous HIV treatment combinations have not worked or have stopped working. Also, it must not be started in patients who have ever been infected with HIV that is resistant to any of the three active substances in the medicine.

The medicine contains the active substances efavirenz, emtricitabine and tenofovir disoproxil and is a 'generic medicine'. This means that it contains the same active substances and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Atripla. For more information on generic medicines, see the question-and-answer document here.

How is the medicine used?

This medicine is available as tablets and can only be obtained with a prescription. Treatment should be started by a doctor who has experience in the management of HIV infection.

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The recommended dose is one tablet daily. It is recommended that the medicine is taken on an empty stomach, preferably at bedtime. Patients should take the medicine regularly and not miss any doses.

If patients need to stop taking one of the active substances in the medicine, or need to take different doses, they will need to change to separate individual medicines. For more information, see the package leaflet.

How does it work?

This medicine contains three active substances: efavirenz, which is a non-nucleoside reverse transcriptase inhibitor (NNRTI); emtricitabine, which is a nucleoside reverse transcriptase inhibitor; and tenofovir disoproxil, which is a 'prodrug' of tenofovir, meaning that it is converted into the active substance tenofovir in the body. Tenofovir is a nucleotide reverse transcriptase inhibitor. Both nucleoside and nucleotide reverse transcriptase inhibitors are commonly known as NRTIs. All three active substances block the activity of reverse transcriptase, an enzyme that allows HIV to reproduce itself in the cells it has infected.

Efavirenz/Emtricitabine/Tenofovir disoproxil Krka keeps the amount of HIV in the blood at a low level. It does not cure HIV infection or AIDS, but it may hold off the damage to the immune system and the development of infections and diseases associated with AIDS.

How has the medicine been studied?

Studies on the benefits and risks of the active substance in the approved use have already been carried out with the reference medicine, Atripla, and do not need to be repeated for Efavirenz/Emtricitabine/Tenofovir disoproxil Krka.

As for every medicine, the company provided studies on its quality. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of this medicine?

Because Efavirenz/Emtricitabine/Tenofovir disoproxil Krka is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is the medicine approved?

The European Medicines Agency concluded that, in accordance with EU requirements, the medicine has been shown to have comparable quality and to be bioequivalent to Atripla. Therefore, the Agency's view was that, as for Atripla, the benefit outweighs the identified risk. The Agency recommended that it be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of this medicine?

The company that markets the medicine will ensure that all doctors expected to prescribe the medicine are provided with an educational pack that includes information on the increased risk of kidney disease with medicines containing tenofovir disoproxil such as this one. The educational pack also contains recommendations for monitoring kidney function in patients taking the medicine.

Recommendations and precautions to be followed by healthcare professionals and patients for its safe and effective use have also been included in the summary of product characteristics and the package leaflet.

Other information about Efavirenz/Emtricitabine/Tenofovir disoproxil Krka

The European Commission granted a marketing authorisation valid throughout the European Union for Efavirenz/Emtricitabine/Tenofovir disoproxil Krka on 8 February 2018.

The full EPAR for Efavirenz/Emtricitabine/Tenofovir disoproxil Krka can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Efavirenz/Emtricitabine/Tenofovir disoproxil Krka, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 02-2018.