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**EPAR summary for the public**

# Efavirenz Teva

efavirenz

This is a summary of the European public assessment report (EPAR) for Efavirenz Teva. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Efavirenz Teva.

## What is Efavirenz Teva?

Efavirenz Teva is a medicine that contains the active substance efavirenz. It is available as tablets (600 mg).

Efavirenz Teva is a 'generic medicine'. This means that Efavirenz Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Sustiva. For more information on generic medicines, see the question-and-answer document here.

## What is Efavirenz Teva used for?

Efavirenz Teva is an antiviral medicine. It is used together with other antiviral medicines to treat adults and children aged three years or older infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

The medicine can only be obtained with a prescription.

## How is Efavirenz Teva used?

Treatment with Efavirenz Teva should be started by a doctor who has experience in the management of HIV infection. Efavirenz Teva must be given in combination with other antiviral medicines. It is recommended that Efavirenz Teva be taken on an empty stomach and without food, preferably at bedtime.

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The recommended dose of Efavirenz Teva for adults is 600 mg once a day. Efavirenz Teva tablets are not suitable for children weighing less than 40 kg. Efavirenz-containing capsules are available for these patients.

The dose of Efavirenz Teva needs to be reduced in patients taking voriconazole (used to treat fungal infections). Patients taking rifampicin (an antibiotic) may need to take a higher dose of Efavirenz Teva.

For full details, see the summary of product characteristics (also part of the EPAR).

## How does Efavirenz Teva work?

The active substance in Efavirenz Teva, efavirenz, is a non-nucleoside reverse transcriptase inhibitor (NNRTI). It blocks the activity of reverse transcriptase, an enzyme produced by HIV that allows it to infect cells in the body and make more viruses. By blocking this enzyme, Efavirenz Teva, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Efavirenz Teva does not cure HIV infection or AIDS, but it may delay the damage to the immune system and the development of infections and diseases associated with AIDS.

## How has Efavirenz Teva been studied?

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

## What are the benefits and risks of Efavirenz Teva?

Because Efavirenz Teva 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 has Efavirenz Teva been approved?

The CHMP concluded that, in accordance with EU requirements, Efavirenz Teva has been shown to have comparable quality and to be bioequivalent to Sustiva. Therefore, the CHMP's view was that, as for Sustiva, the benefit outweighs the identified risk. The Committee recommended that Efavirenz Teva be given marketing authorisation.

## Other information about Efavirenz Teva

The European Commission granted a marketing authorisation valid throughout the European Union for Efavirenz Teva on 9 January 2012.

The full EPAR for Efavirenz Teva 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 Teva, 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 11-2011.