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EPAR summary for the public

Nevirapine Teva

nevirapine

This is a summary of the European public assessment report (EPAR) for Nevirapine 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 Nevirapine Teva.

What is Nevirapine Teva?

Nevirapine Teva is a medicine that contains the active substance nevirapine. It is available as tablets (200 mg).

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

What is Nevirapine Teva used for?

Nevirapine Teva is an antiviral medicine. It is used in combination with other antiviral medicines to treat patients 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 Nevirapine Teva used?

Treatment with Nevirapine Teva should be given by a doctor who has experience in the treatment of HIV infection.

Nevirapine Teva is never taken on its own. It must be taken with at least two other antiviral medicines. Because the medicine can cause serious rash, treatment starts with 200 mg once a day for two weeks, before increasing the dose to the standard dose of 200 mg twice a day. The dose should not be

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increased to the full twice-daily dose until any rash has cleared. If the patient cannot switch to the twice-daily dose within four weeks of starting Nevirapine Teva, alternative treatments should be sought.

How does Nevirapine Teva work?

The active substance in Nevirapine Teva, nevirapine, is a non-nucleoside reverse transcriptase inhibitor (NNRTI). It blocks the activity of reverse transcriptase, an enzyme produced by HIV-1 that allows it to infect cells in the body and make more viruses. By blocking this enzyme, Nevirapine Teva, taken in combination with other antiviral medicines, reduces the amount of HIV-1 in the blood and keeps it at a low level. Nevirapine Teva does not cure HIV-1 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 Nevirapine Teva been studied?

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

What are the benefits and risks of Nevirapine Teva?

Because Nevirapine Teva is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as the reference medicine.

Why has Nevirapine Teva been approved?

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

Other information about Nevirapine Teva

The European Commission granted a marketing authorisation valid throughout the EU for Nevirapine Teva on 30 November 2009.

The full EPAR for Nevirapine 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 Nevirapine 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 07-2014.