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EPAR summary for the public

Emtriva

emtricitabine

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

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

What is Emtriva and what is it used for?

Emtriva is an antiviral medicine for treating adults and children infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

Emtriva is used in combination with other antiviral medicines and contains the active substance emtricitabine.

How is Emtriva used?

Emtriva is available as capsules (200 mg) and as a solution (10 mg/ml) to be taken by mouth. The usual dose of Emtriva is one capsule once a day for patients who weigh 33 kg or more. The oral solution is for patients who weigh less than 33 kg, and those who cannot swallow the capsules. The usual dose of oral solution is 6 mg per kilogram body weight once a day, up to a maximum of 240 mg (24 ml). The dose may need to be adjusted in patients who have problems with their kidneys.

For patients who have taken medicines to treat their HIV infection before and did not respond to that treatment, doctors should only prescribe Emtriva once they have looked at the antiviral medicines the patient has taken before and assessed the likelihood of the virus's response to any new antiviral medicines that might be prescribed.

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Emtriva should only be started by a doctor experienced in managing HIV infections. The medicine can only be obtained with a prescription.

How does Emtriva work?

The active substance in Emtriva, emtricitabine, is a nucleoside reverse transcriptase inhibitor (NRTI). It blocks the activity of reverse transcriptase, an enzyme made by the virus that allows it to reproduce itself in the cells it has infected. Emtriva, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Emtriva does not cure HIV infection or AIDS, but it can hold off the damage to the immune system and the development of infections and diseases associated with AIDS.

What benefits of Emtriva have been shown in studies?

Studies have shown that Emtriva, in combination with other antiviral medicines, reduces viral loads in HIV-infected patients and compares well with other medicines used in combination. The results from three main studies are as follows:

- In a study of 571 previously untreated adults, more patients taking Emtriva (in combination with didanosine and efavirenz) had viral loads below 50 copies/ml after 24 weeks of treatment than those taking stavudine (81% and 70%, respectively). This difference was maintained after 48 weeks of treatment (73% and 56%).
- In another study in 468 previously untreated patients, Emtriva was as effective as lamivudine (both taken in combination with stavudine and either efavirenz or nevirapine). In this study after 48 weeks, around two thirds of the patients had viral loads below 400 copies/ml, and slightly fewer had viral loads below 50 copies/ml.
- In a third study in 459 patients who had been taking three antiviral medicines (including lamivudine), the number of patients switching from lamivudine to Emtriva who had viral loads below 400 copies/ml after 48 weeks was similar to the number of those who continued taking lamivudine (73% and 82%, respectively).

Similar results on effectiveness were seen in two studies involving 120 children and adolescents taking Emtriva in combination with other antiviral medicines.

What is the risk associated with Emtriva?

The most common side effects with Emtriva (seen in more than 1 patient in 10) are headache, diarrhoea, nausea (feeling sick), and elevated creatine kinase levels in the blood (an enzyme found in muscles). Skin discoloration was very common in children. For the full list of side effects and restrictions, see the package leaflet.

Why is Emtriva approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Emtriva's benefits are greater than its risks for the treatment of HIV-1 infected adults and children in combination with other antiretroviral agents. The Committee noted that this indication is based on studies in patients who have not received HIV treatment before, or whose HIV is already well controlled with antiviral medicines, and that there was no experience of Emtriva in patients whose previous treatment for HIV was not working. The Committee recommended that it be given marketing authorisation.

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

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

Other information about Emtriva:

The European Commission granted a marketing authorisation valid throughout the European Union for Emtriva on 24 October 2003.

The full EPAR for Emtriva 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 Emtriva, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2016.