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Evotaz (*atazanavir / cobicistat*)

An overview of Evotaz and why it is authorised in the EU

What is Evotaz and what is it used for?

Evotaz is an antiviral medicine used in combination with other medicines to treat human immunodeficiency virus type 1 (HIV-1) infection in adults and in adolescents aged 12 years and above weighing at least 35 kg. HIV-1 is a virus that causes acquired immune deficiency syndrome (AIDS).

Evotaz contains the active substances atazanavir and cobicistat. The medicine is for use only in patients whose infection is not expected to be resistant to atazanavir.

How is Evotaz used?

Evotaz can only be obtained with a prescription, and treatment should be started by a doctor experienced in managing HIV infection. Evotaz is available as tablets that contain atazanavir and cobicistat. The recommended dose is one tablet a day, taken with food.

How does Evotaz work?

Evotaz contains two active substances: atazanavir and cobicistat. Atazanavir is a protease inhibitor that blocks an HIV enzyme, called HIV protease, from working. The virus needs HIV protease to make more viruses. When the enzyme is blocked, the virus cannot reproduce and its spread in the body slows down. Cobicistat acts as a 'booster' that increases the level of atazanavir in the blood by slowing its breakdown, which boosts atazanavir's antiviral effect.

Evotaz, taken with other HIV medicines, reduces HIV-1 in the blood and keeps the virus at a low level. It does not cure HIV infection, but it can hold off damage to the immune system and avoid the development of infections and diseases associated with AIDS.

The active substances in Evotaz are also available in the EU as individual medicines: atazanavir is available as Reyataz and cobicistat as Tybost.

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What benefits of Evotaz have been shown in studies?

Because atazanavir and cobicistat have both previously been shown to be effective and are authorised for use in the treatment of HIV-1 infection, studies were mainly carried out to show that Evotaz produced levels of atazanavir in the blood similar to those produced by the two active substances given separately or by atazanavir given with a different booster medicine, ritonavir (an established combination).

In addition, the use of atazanavir with cobicistat has been evaluated in one main study in 698 HIV patients who had not been treated previously. Atazanavir and cobicistat were compared with atazanavir and ritonavir; all patients also received the HIV medicines emtricitabine and tenofovir disoproxil. The main measure of effectiveness was the proportion of patients in whom the HIV-1 count in the blood (known as viral load) was reduced to less than 50 copies/ml after 48 weeks of treatment. Overall, 85% of patients (293 out of 344) treated with atazanavir and cobicistat achieved this reduction, which was comparable to 87% of patients (304 of 348) who achieved it with atazanavir and ritonavir.

The use of atazanavir with cobicistat has also been evaluated in a study involving 14 adolescents aged 12 to 17 years old and weighing at least 35 kg, whose HIV infection was well controlled on a combination of three HIV medicines that included two from the class of nucleoside reverse transcriptase inhibitors (NRTI). The patients received atazanavir with cobicistat in addition to the two existing NRTIs. After 48 weeks, HIV infection remained well controlled (meaning the viral load was below 50 copies/ml) in 93% of patients (13 out of 14 patients).

What are the risks associated with Evotaz?

The most common side effects with Evotaz (which may affect more than 1 in 10 people) are jaundice, which may show as yellow discoloration of the eye, and nausea (feeling sick).

For the full list of all side effects reported with Evotaz, see the package leaflet.

Evotaz must not be taken by patients who have moderately or severely reduced liver function. It must also not be taken by patients using certain medicines because of the possibility of interactions that could be harmful. For the full list of restrictions, see the package leaflet.

Why is Evotaz authorised in the EU?

Both active substances have already been shown to be effective and Evotaz may be a useful substitute for atazanavir accompanied by ritonavir as a booster. Combining atazanavir and cobicistat in a single tablet has the potential of simplifying the dosing regimen. Evotaz has also been shown to be effective in adolescents whose HIV infection is well controlled on existing treatment. Evotaz's side effects were similar to those that occur with the individual medicines.

The European Medicines Agency therefore decided that Evotaz's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Evotaz are continuously monitored. Suspected side effects reported with Evotaz are carefully evaluated and any necessary action taken to protect patients.

Other information about Evotaz

Evotaz received a marketing authorisation valid throughout the European Union on 13 July 2015.

Further information on Evotaz can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/evotaz.

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