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Tybost (*cobicistat*)

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

What is Tybost and what is it used for?

Tybost is a medicine for treating adults and adolescents from 12 years of age (and over a certain weight) who are infected with HIV-1, a virus that causes acquired immune deficiency syndrome (AIDS).

Tybost does not treat HIV directly but is given to boost the effects of atazanavir or darunavir, which are used with other standard medicines to treat HIV-1.

It contains the active substance cobicistat.

How is Tybost used?

Tybost is available as tablets (150 mg). The recommended dose is one tablet per day, taken with food. Tybost is given together with 300 mg atazanavir once per day (in patients weighing at least 35 kg) or with 800 mg darunavir once per day (in patients weighing at least 40 kg).

Tybost can only be obtained with a prescription. Treatment should be started by a doctor who is experienced in managing HIV infection. For more information about using Tybost, see the package leaflet or contact your doctor or pharmacist.

How does Tybost work?

The active substance in Tybost, cobicistat, blocks the action of a group of liver enzymes called CYP3A, which are involved in breaking down medicines in the body. By blocking CYP3A, Tybost slows down the rate at which atazanavir and darunavir are broken down, allowing them to work for longer.

Tybost is taken with atazanavir or darunavir, both of which are protease inhibitors: they block an enzyme called protease that is involved in the reproduction of the HIV-1 virus. When the enzyme is blocked, the virus cannot reproduce normally, which slows down the spread of infection.

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Treatment with Tybost and atazanavir or darunavir does not cure HIV-1 infection or AIDS, but it can hold off damage to the immune system and the development of infections and diseases associated with AIDS, when combined with other standard HIV-1 medicines.

What benefits of Tybost have been shown in studies?

A main study in patients infected with HIV-1 showed that Tybost was as effective as another booster medicine, ritonavir.

In this study, both medicines were used to boost the effects of atazanavir, in combination with another standard HIV-1 medicine containing emtricitabine and tenofovir. After 48 weeks, around 85% of patients given Tybost had very low levels of HIV-1 (< 50 RNA copies/ml), compared with around 87% of patients given ritonavir.

Further data indicated that Tybost was effective as a booster medicine with atazanavir or darunavir in adolescents between 12 and 17 years of age.

What are the risks associated with Tybost?

The most common side effects with Tybost (which may affect more than 1 in 10 people) when given with atazanavir are ocular icterus (yellowing of the whites of the eyes), nausea (feeling sick) and jaundice (yellowing of the skin and eyes). For the full list of side effects of Tybost, see the package leaflet.

Tybost must not be taken together with a number of other medicines that affect the way Tybost is broken down or whose action is affected by Tybost. For the full list of restrictions, see the package leaflet.

Why is Tybost authorised in the EU?

Studies showed that Tybost was as effective as ritonavir as a booster for atazanavir, and a similar effect is expected for darunavir based on data on the impact of Tybost on the darunavir levels in the body. Furthermore, there were no safety concerns preventing Tybost from being used together with atazanavir or darunavir.

The European Medicines Agency therefore decided that Tybost'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 Tybost?

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

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

Other information about Tybost

Tybost received a marketing authorisation valid throughout the EU on 19 September 2013.

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

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