EMA/471818/2013
EMEA/H/C/002572

EPAR summary for the public

Tybost

cobicistat

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

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

What is Tybost and what is it used for?

Tybost is a medicine that contains the active substance cobicistat. It is used in the treatment of adults 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.

How is Tybost used?

Tybost can only be obtained with a prescription. Treatment should be started by a doctor who is experienced in managing HIV infection.

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 or with 800 mg darunavir once per day. For further information, see the package leaflet.

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, thereby prolonging the length of time they act in the body.

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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.

Treatment with Tybost and atazanavir or darunavir 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, when combined with other standard HIV-1 medicines.

What benefits of Tybost have been shown in studies?

Tybost was compared with another medicine called ritonavir in one main study involving 698 patients infected with HIV-1. The study compared these two medicines when used to boost the effects of atazanavir, given in combination with another standard HIV-1 medicine containing emtricitabine and tenofovir. The main measure of effectiveness was based on the reduction in viral load (the amount of virus found in the blood): patients who attained a viral load of less than 50 HIV-1 RNA copies/ml after 48 weeks of treatment were considered to have responded to treatment. Tybost was shown to be as effective as ritonavir: around 85% of patients (293 out of 344 patients) given Tybost responded to treatment, compared with around 87% of patients (304 out of 348 patients) given ritonavir.

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 all side effects reported with 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: alfuzosin (used to treat an enlarged prostate gland); amiodarone or quinidine (used to correct irregular heartbeat); carbamazepine, phenobarbital, or phenytoin (used to prevent seizures); rifampicin (used to prevent and treat tuberculosis and other infections); dihydroergotamine, ergometrine or ergotamine (used to treat migraine headache); cisapride (used to relieve certain stomach problems); St. John's wort (a herbal remedy used for depression and anxiety); lovastatin or simvastatin (used to lower blood cholesterol); pimozide (used to treat abnormal thoughts or feelings); sildenafil (used to treat pulmonary arterial hypertension); and oral midazolam or triazolam (used to aid sleep or relieve anxiety). For the full list of restrictions, see the package leaflet.

Why is Tybost approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Tybost's benefits are greater than its risks and recommended that it be approved for use 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. The CHMP considered that there were no safety concerns preventing Tybost from being used together with atazanavir or darunavir.

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

A risk management plan has been developed to ensure that Tybost is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the

package leaflet for Tybost, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Tybost

The European Commission granted a marketing authorisation valid throughout the European Union for Tybost on 19 September 2013.

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

This summary was last updated in 09-2013.