EMA/599498/2014
EMEA/H/C/002819

EPAR summary for the public

Rezolsta

darunavir / cobicistat

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

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

What is Rezolsta and what is it used for?

Rezolsta is an antiviral medicine used, in combination with other medicines, to treat adults with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

Rezolsta contains the active substances darunavir and cobicistat. The medicine is for use only in patients who have not received HIV treatment before or previously treated patients whose disease is not expected to be resistant to darunavir and who are healthy enough and have HIV virus levels below a certain threshold.

How is Rezolsta used?

Rezolsta can only be obtained with a prescription and treatment should only be started by a doctor who is experienced in managing HIV infection. Rezolsta is available as tablets that contain 800 mg of darunavir and 150 mg of cobicistat. The recommended dose is one tablet a day, taken with food. For further information, see the package leaflet.

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How does Rezolsta work?

Rezolsta contains two active substances. Darunavir is a protease inhibitor. It blocks an enzyme called protease, which the HIV virus needs to make new copies of itself. When the enzyme is blocked, the virus does not reproduce normally and its increase and spread slows down. Cobicistat acts as a 'booster' to enhance the effects of darunavir, by prolonging the time in which it acts in the body.

Rezolsta, taken in combination with other HIV medicines, reduces the amount of HIV in the blood and keeps it at a low level. Rezolsta does not cure HIV infection or AIDS, but it can delay or reverse the damage to the immune system and the development of infections and diseases associated with AIDS.

Darunavir is currently authorised as Prezista and cobicistat as Tybost.

What benefits of Rezolsta have been shown in studies?

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

In addition, one main study was carried out to examine the safety and effectiveness of darunavir and cobicistat given with other HIV medicines, in 313 adult patients with HIV who had not been previously treated or who had been previously treated and whose infection was not expected to be resistant to darunavir. Effectiveness was measured by a reduction in viral load (the amount of HIV-1 virus in the blood) to less than 50 copies/ml. Overall, 258 patients (82%) achieved this response after 24 weeks of treatment, and 253 patients (81%) at 48 weeks, which was comparable to results previously seen with darunavir plus ritonavir.

What are the risks associated with Rezolsta?

The most common side effects with Rezolsta (which may affect more than 1 in 10 people) are diarrhoea, nausea (feeling sick), and rash. The most serious side effects were rash, diabetes, hypersensitivity (allergic) reactions, vomiting, and 'immune reconstitution syndrome'. Immune reconstitution syndrome happens when the patient's immune system starts working again and fights existing infections, causing inflammation at the site of the infection. For the full list of all side effects reported with Rezolsta, see the package leaflet.

Rezolsta must not be taken by patients who have severely reduced liver function. It must also not be used together with certain other medicines as it may interact with them, thereby reducing the effectiveness of treatment or increasing the risk of side effects. For the full list of restrictions, see the package leaflet.

Why is Rezolsta approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Rezolsta's benefits are greater than its risks and recommended that it be approved for use in the EU. Both active substances have already been shown to be effective, and combining them into a single tablet was considered to be more convenient than taking them separately, reducing the risk of errors. In addition there was no evidence of unexpected safety concerns.

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

A risk management plan has been developed to ensure that Rezolsta 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 Rezolsta, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Rezolsta

The European Commission granted a marketing authorisation valid throughout the European Union for Rezolsta on 19/11/2014.

The full EPAR and risk management plan summary for Rezolsta 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 Rezolsta, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2014.