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Rezolsta *(darunavir/cobicistat)*

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

What is Rezolsta and what is it used for?

Rezolsta is a medicine used for treating people with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). It is given in combination with other HIV medicines for treating adults and children from 6 years of age (and weighing at least 25 kg).

Rezolsta contains the active substances darunavir and cobicistat. The medicine is for use only in patients who have not received HIV treatment before or in 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 be started by a doctor experienced in managing HIV infection. Rezolsta is available as tablets, to be taken once a day with food.

For more information about using Rezolsta, see the package leaflet or contact your doctor or pharmacist.

How does Rezolsta work?

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 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 examined the safety and effectiveness of darunavir and cobicistat given with other HIV medicines in 313 adults with HIV infection who had not been treated previously or who had been 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 with darunavir plus ritonavir.

Further data indicated that darunavir and cobicistat also led to acceptable reductions in the viral load in adolescents between 12 and 17 years of age. Additional data showed that the way darunavir and cobicistat behave in the body is similar in adults, adolescents and children from the age of 6 years; therefore, darunavir and cobicistat are expected to have a similar effect in these age groups.

What are the risks associated with Rezolsta?

For the full list of side effects and restrictions with Rezolsta, see the package leaflet.

The most common side effects with Rezolsta (which may affect more than 1 in 10 people) include diarrhoea, nausea (feeling sick), headache and rash.

The most serious side effects were rash, diabetes, hypersensitivity (allergic) reactions, vomiting, Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals) and immune reconstitution syndrome. With immune reconstitution syndrome, the patient's immune system starts working again and fights existing infections (causing inflammation) and may attack healthy tissue such as the liver and thyroid gland.

Rezolsta must not be taken by patients who have severely reduced liver function. It must also not be used with certain other medicines as they may reduce the effectiveness of treatment or increase side effects.

Why is Rezolsta authorised in the EU?

The European Medicines Agency decided that Rezolsta's benefits are greater than its risks and that it can be authorised 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. There was no evidence of unexpected side effects.

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

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

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

Other information about Rezolsta

Rezolsta received a marketing authorisation valid throughout the EU on 19 November 2014.

Further information on Rezolsta can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/rezolsta

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