EMA/449132/2016
EMEA/H/C/004048

EPAR summary for the public

Atazanavir Mylan

atazanavir

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

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

What is Atazanavir Mylan and what is it used for?

Atazanavir Mylan is an HIV medicine used to treat patients infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immunodeficiency syndrome (AIDS). It is used together with low-dose ritonavir and other antiviral medicines to treat patients aged 6 years and over.

Doctors should prescribe Atazanavir Mylan only after they have looked at which medicines the patient has taken and carried out tests to establish that the virus is likely to respond to Atazanavir Mylan. The medicine is not expected to work in patients in whom many medicines in the same class as Atazanavir Mylan (protease inhibitors) do not work.

Atazanavir Mylan contains the active substance atazanavir.

Atazanavir Mylan is a 'generic medicine'. This means that Atazanavir Mylan is similar to a 'reference medicine' already authorised in the European Union (EU) called Reyataz. For more information on generic medicines, see the question-and-answer document here.

How is Atazanavir Mylan used?

Atazanavir Mylan is available as capsules (150 mg, 200 mg and 300 mg). It can only be obtained with a prescription and treatment should be started by a doctor who has experience in the treatment of HIV infection.

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For adults, the recommended dose is 300 mg once a day. In younger patients, the dose of Atazanavir Mylan depends on body weight. Each dose must be taken with food.

Atazanavir Mylan is normally given with ritonavir to boost its action but doctors can consider stopping ritonavir in adults in some specific situations.

How does Atazanavir Mylan work?

The active substance in Atazanavir Mylan, atazanavir, is a protease inhibitor. It blocks an enzyme called protease, which is needed for the virus to multiply. Blocking the enzyme prevents the virus from multiplying, slowing down the spread of infection. A small dose of another medicine, ritonavir, is normally given at the same time as a 'booster'. Ritonavir slows down the break-down of atazanavir, increasing the levels of atazanavir in the blood. This allows a lower dose of atazanavir to be used for the same antiviral effect. Atazanavir Mylan, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Atazanavir Mylan does not cure HIV infection or AIDS, but it may delay the damage to the immune system and the development of infections and diseases associated with AIDS.

How has Atazanavir Mylan been studied?

Because Atazanavir Mylan is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Reyataz. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Atazanavir Mylan?

Because Atazanavir Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Atazanavir Mylan approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Atazanavir Mylan has been shown to have comparable quality and to be bioequivalent to Reyataz. Therefore, the CHMP's view was that, as for Reyataz, the benefit outweighs the identified risk. The Committee recommended that Atazanavir Mylan be approved for use in the EU.

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

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

Other information about Atazanavir Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Atazanavir Mylan on 22 August 2016.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 08-2016.