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## Atazanavir Viatris<sup>1</sup> (*atazanavir*)

An overview of Atazanavir Viatris and why it is authorised in the EU

### What is Atazanavir Viatris and what is it used for?

Atazanavir Viatris 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 Viatris 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 Viatris. The medicine is not expected to work in patients in whom many medicines in the same class as Atazanavir Viatris (protease inhibitors) do not work.

Atazanavir Viatris contains the active substance atazanavir and is a 'generic medicine'. This means that Atazanavir Viatris contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Atazanavir Viatris is Reyataz. For more information on generic medicines, see the question-and-answer document [here](#).

### How is Atazanavir Viatris used?

Atazanavir Viatris is available as capsules. 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.

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

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

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

### How does Atazanavir Viatris work?

The active substance in Atazanavir Viatris, 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

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<sup>1</sup> Previously known as Atazanavir Mylan.

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 Viatris, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Atazanavir Viatris 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 Viatris been studied?**

Studies on the benefits and risks of the active substance in the authorised use have already been carried out in the reference medicine, Reyataz, and do not need to be repeated for Atazanavir Viatris.

As for every medicine, the company provided studies on the quality of Atazanavir Viatris. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

## **What are the benefits and risks of Atazanavir Viatris?**

Because Atazanavir Viatris 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 Viatris authorised in the EU?**

The European Medicines Agency concluded that, in accordance with EU requirements, Atazanavir Viatris has been shown to have comparable quality and to be bioequivalent to Reyataz. Therefore, the Agency's view was that, as for Reyataz, the benefits of Atazanavir Viatris outweigh the identified risks and it can be authorised for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Atazanavir Viatris ?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Atazanavir Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Reyataz also apply to Atazanavir Viatris where appropriate.

As for all medicines, data on the use of Atazanavir Viatris are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Atazanavir Viatris**

Atazanavir Mylan received a marketing authorisation valid throughout the EU on 22 August 2016.

The name of the medicine was changed to Atazanavir Viatris on 29 July 2024.

Further information on Atazanavir Viatris can be found on the Agency's website:

[ema.europa.eu/en/medicines/human/EPAR/atazanavir-viatris-previously-atazanavir-mylan](https://ema.europa.eu/en/medicines/human/EPAR/atazanavir-viatris-previously-atazanavir-mylan).

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 08-2024.