EMA/107659/2019
EMEA/H/C/004859

Atazanavir Krka (*atazanavir*)

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

What is Atazanavir Krka and what is it used for?

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

Atazanavir Krka contains the active substance atazanavir and is a 'generic medicine'. This means that Atazanavir Krka contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Reyataz. For more information on generic medicines, see the question-and-answer document here.

How is Atazanavir Krka used?

Atazanavir Krka 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.

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

Atazanavir Krka 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 Krka, see the package leaflet or contact your doctor or pharmacist.

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

How does Atazanavir Krka work?

The active substance in Atazanavir Krka, atazanavir, is a protease inhibitor. It blocks an enzyme called protease, which is needed for the HIV 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 Krka, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Atazanavir Krka does not cure HIV infection or AIDS but, when used in combination with other antivirals, it holds off the damage to the immune system and the development of infections and diseases associated with AIDS.

How has Atazanavir Krka been studied?

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

As for every medicine, the company provided studies on the quality of Atazanavir Krka. 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 Krka?

Because Atazanavir Krka 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 Krka authorised in the EU?

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

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

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

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

Other information about Atazanavir Krka

Atazanavir Krka received a marketing authorisation valid throughout the EU on 25 March 2019.

Further information on Atazanavir Krka can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/atazanavir-krka. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 03-2019.