LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Atazanavir Teva
(atazanavir)

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Hard capsules, 150 mg, 200 mg and 300 mg

This is a summary of the public assessment report (PAR) for Atazanavir Teva. It explains how Atazanavir Teva was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Atazanavir Teva.

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

What is Atazanavir Teva and what is it used for?

Atazanavir Teva is a 'generic medicine'. This means that Atazanavir Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Reyataz. Atazanavir Teva is used in the treatment of Human Immunodeficiency Virus (HIV) infection and may be used by adults and children 6 years of age and older.

How does Atazanavir Teva work?

Atazanavir Teva control HIV infection by stopping a protein that the HIV needs for its multiplication. They work by reducing the amount of HIV in your body and this in turn, strengthens your immune system. In this way Atazanavir Teva reduces the risk of developing illnesses linked to HIV infection.

How is Atazanavir Teva used?

The pharmaceutical form of Atazanavir Teva is hard capsule for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Atazanavir Teva have been shown in studies?

Because Atazanavir Teva is a generic medicine, studies in patients 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 possible side effects of Atazanavir Teva?

Because Atazanavir Teva is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Atazanavir Teva approved?

It was concluded that, in accordance with EU requirements, Atazanavir Teva has been shown to have comparable quality and to be bioequivalent to the reference medicine Reyataz. Therefore, the Medical Products Agency in Sweden decided that, as for Reyataz, the benefits are greater than its risks and recommended that it can be approved for use.

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

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

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Atazanavir Teva

The marketing authorisation for Atazanavir Teva was granted on 2016-01-21 in Sweden.

The full PAR for Atazanavir Teva can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Atazanavir Teva, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2016-01.