**WHO Prequalification Programme**
**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

# Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets [1]

International Nonproprietary Name (INN)
atazanavir (as sulfate), ritonavir

## Abstract

Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets (HA632), manufactured at Cipla Ltd, Unit II, A-42, MIDC, Patalganga, District-Raigad, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 21 April 2017.

Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets is indicated for the treatment of HIV-1 infected adults and children weighing at least 39 kg, in combination with other antiretroviral medicinal products. Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients (APIs) of Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets are the protease inhibitors atazanavir and ritonavir, well established and documented agents for the treatment of HIV/AIDS in combination with other products.

Atazanavir and ritonavir have been investigated in combination therapy in several clinical trials in both treatment-naïve and treatment-experienced patients. These studies have demonstrated significant decreases in HIV-1 viral load and increases in CD4 cell count. Clinical end-point data indicate that atazanavir and ritonavir, in combination with other antiretroviral agents, result in a significant reduction in the risk of disease progression and mortality.

The most frequent adverse events observed during treatment were symptoms linked to elevated bilirubin levels such as jaundice or ocular icterus, gastrointestinal symptoms such as vomiting or diarrhea, headache, rash and fatigue.

The most serious safety concerns with atazanavir and ritonavir are nephrolithiasis, Stevens Johnson syndrome and changes in the electrocardiogram, i.e. PR interval prolongation (caution should be exercised in patients with pre-existing cardiac conduction abnormalities and if considering administering atazanavir with other medicinal products which can increase the QT interval, due to the risk of cardiac dysrhythmias).

The risk/benefit profile of atazanavir and ritonavir shows an acceptable safety profile and adequate antiretroviral activity.

The efficacy and safety profile of Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets is well established based on extensive clinical experience in the treatment of HIV.

On the basis of data submitted and public information on the use of combination therapy in HIV/AIDS, the team of assessors advised that Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets in the list of prequalified medicinal products.

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

***Summary of Prequalification Status for Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets:***

| | **Initial Acceptance** | | | | | |
|---|---|---|---|---|---|---|
| | **Date** | **Outcome** | | | | |
| Status on PQ list, i.e. date of listing | 21 April 2017 | | | | | |
| **Dossier Evaluation (Quality assurance)** | | | | | | |
| Quality | 16 March 2017 | MR | | | | |
| Bioequivalence | 28 March 2017 | MR | | | | |
| **Inspection Status** | | | | | | |
| GMP(re-)inspection | | | | | | |
| API | 16 April 2014 | MR | | | | |
| API | 14 March 2016 | MR | | | | |
| FPP | 21 Feb 2014 | MR | | | | |
| GCP/GLP (re-)inspection | 18 May 2012 | NA | | | | |

MR: meets requirements
NA: not applicable, not available