Atazanavir Krka

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, please also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	This was an application for a group of	03/06/2025		SmPC and PL	To update sections 4.3 and 4.4 of the SmPC in

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000273939	variations. C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2.a - To update sections 4.3 and 4.4 of the SmPC in order to clarify the contraindication for the co-administration of atazanavir with strong inducers of CYP3A4, based on the results from study AI424082. The change follows assessment of the change for the reference product, Reyataz (EMEA/H/C/000494/II/0141/G). C.I.2.a - To update sections 4.3 and 4.5 in order to add drug-drug interaction information with antiplatelet therapies classified as P2Y12 platelet inhibitors (ticagrelor, clopidogrel and				order to clarify the contraindication for the co-administration of atazanavir with strong inducers of CYP3A4, based on the results from study AI424082. The change follows assessment of the change for the reference product, Reyataz (EMEA/H/C/000494/II/0141/G). To update sections 4.3 and 4.5 in order to add drug-drug interaction information with antiplatelet therapies classified as P2Y12 platelet inhibitors (ticagrelor, clopidogrel and prasugrel), dexamethasone or other corticosteroids, antineoplastics encorafenib or ivosidenib, gonadotropin-releasing hormone (GnRH) receptor antagonist elagolix, kinase inhibitor fostamatinib and antineoplastic apalutamide based on the cumulative review of literature search. The PL has been updated accordingly. The change follows assessment of the change for the reference product, Reyataz (EMEA/H/C/000494/II/0137).

	prasugrel), dexamethasone or other corticosteroids, antineoplastics encorafenib or ivosidenib, gonadotropin-releasing hormone (GnRH) receptor antagonist elagolix, kinase inhibitor fostamatinib and antineoplastic apalutamide based on the cumulative review of literature search. The PL has been updated accordingly. The change follows assessment of the change for the reference product, Reyataz (EMEA/H/C/000494/II/0137). Additionally, the MAH took the opportunity to implement editorial changes to the PI in EN, RO, IS and HU to align with the reference product PI, correct for missing wording, and to correct for typographic errors. Furthermore, the MAH took the opportunity to remove the United Kingdom (Northern Ireland) from the list of local representatives in the PL for all countries, in addition to an update to the contact information for the local representative for HR.				