Summary of risk management plan for Atazanavir Krka (atazanavir)

This is a summary of the risk management plan (RMP) for Atazanavir Krka. The RMP details important risks of Atazanavir Krka and how more information will be obtained about Atazanavir Krka's risks and uncertainties (missing information).

Atazanavir Krka's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Atazanavir Krka should be used.

This summary of the RMP for Atazanavir Krka should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Atazanavir Krka's RMP.

I. The medicine and what it is used for

Atazanavir Krka capsules, co-administered with low dose ritonavir, are indicated for the treatment of HIV-1 infected adults and paediatric patients 6 years of age and older in combination with other antiretroviral medicinal products. It contains atazanavir as the active substance and it is given orally.

Further information about the evaluation of Atazanavir Krka's benefits can be found in Atazanavir Krka's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/atazanavir-krka.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Atazanavir Krka together with measures to minimise such risks and the proposed studies for learning more about Atazanavir Krka's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;

- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Atazanavir Krka are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Atazanavir Krka Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

Summary of safety concerns	
Important identified risks	PR interval prolongation (both paediatric and adult populations)
	Neprolithiasis with or without alteration of the renal function
	Hyperbilirubinemia
	Severe skin reactions
	Cholelithiasis
	Angioedema
	Immune reconstitution inflammatory syndrome (IRIS)
	Chronic kidney disease
Important potential risks	QT prolongation
	Kernicterus
	Acute renal failure (adults)
	Interstitial nephritis

Summary of safety concerns	
	Lack of efficacy due to unboosted ATV "off-label use"
Missing information	Hepatic impairment
	Pregnancy
	Paediatric patients < 3 months of age
	Geriatric patients
	Woman who are breastfeeding

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Atazanavir Krka.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Atazanavir Krka.