Part VI: Summary of the risk management plan

Summary of risk management plan for Nilotinib STADA 50, 150, 200 mg kemény kapszula and Nilotinib STADA Arzneimittel AG 50, 150, 200 mg kemény kapszula (Nilotinib)

This is a summary of the risk management plan (RMP) for Nilotinib STADA 50, 150, 200 mg kemény kapszula, Nilotinib STADA Arzneimittel AG 50, 150, 200 mg kemény kapszula (Nilotinib STADA and Nilotinib STADA Arzneimittel AG). The RMP details important risks of Nilotinib STADA and Nilotinib STADA Arzneimittel AG, how these risks can be minimised, and how more information will be obtained about Nilotinib STADA's and Nilotinib STADA Arzneimittel AG 's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Nilotinib STADA's and Nilotinib STADA Arzneimittel AG's RMP.

I. The medicine and what it is used for

Nilotinib STADA and Nilotinib STADA Arzneimittel AG are indicated in the treatment of:

- adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase
- adult patients with chronic phase and accelerated phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib. Efficacy data in patients with CML in blast crisis are not available
- paediatric patients with chronic phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib.

It contains nilotinib hydrochloride dihydrate as the active substance and it is given by hard capsule of 50mg, 150mg and 200mg.

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

Important risks of Nilotinib STADA and Nilotinib STADA Arzneimittel AG, together with measures to minimise such risks and the proposed studies for learning more about Nilotinib STADA's and Nilotinib STADA Arzneimittel AG'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 so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of nilotinib is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Nilotinib STADA and Nilotinib STADA Arzneimittel AG 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 Nilotinib STADA and Nilotinib STADA Arzneimittel AG. 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	• Significant bleeding • Severe infections • Growth retardation
Important potential risks	• Reproductive toxicity/pregnancy

Summary of safety concerns	
	• Skin malignancy
Missing information	• Pediatric patients below 2 years of age

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 Nilotinib STADA and Nilotinib STADA Arzneimittel AG.

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

There are no studies required for Nilotinib STADA and Nilotinib STADA Arzneimittel AG.