Part VI: Summary of the risk management plan

Summary of risk management plan for Voriconazole Stada 10 mg/ml concentrate for solution for infusion (Voriconazole)

This is a summary of the risk management plan (RMP) for Voriconazole Stada. The RMP details important risks of Voriconazole Stada, how these risks can be minimised, and how more information will be obtained about Voriconazole Stada's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Voriconazole Stada is authorised is indicated in adults and children aged 2 years and above as follows:

- Treatment of invasive aspergillosis.
- Treatment of candidaemia in non-neutropenic patients.
- Treatment of fluconazole-resistant serious invasive *Candida* infections (including *C. krusei*).
- Treatment of serious fungal infections caused by *Scedosporium* spp. and *Fusarium* spp.

Voriconazole 10 mg/ml concentrate for solution for infusion should be administered primarily to patients with progressive, possibly life-threatening infections. Prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem cell transplant (HSCT) recipients (see SmPC for the full indication). It contains voriconazole as the active substance and it is given intravenously.

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

Important risks of Voriconazole Stada, together with measures to minimise such risks and the proposed studies for learning more about Voriconazole Stada'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 the case of Voriconazole Stada, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

II.A List of important risks and missing information

Important risks of Voriconazole Stada are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Voriconazole Stada. 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);

List of important risks and missing information	
Important identified risks	• Hepatic toxicity • Phototoxicity • Squamous cell carcinoma
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Hepatic toxicity Important identified risk	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> *SmPC section 4.4 and 4.8* – Restricted medical prescription <u>Additional risk minimisation measures:</u> - *Educational material for healthcare professionals. The educational material shall consist of Healthcare Professional Question and Answer Brochure, Healthcare Professional Checklist. For key elements of the educational material see Annex 6.*

Phototoxicity Important identified risk	
Risk minimisation measures	<u>Routine risk minimisation measures:</u>

	SmPC section 4.4 and 4.8 – Restricted medical prescription Additional risk minimisation measures: - *Educational material for healthcare professionals and patients. Healthcare Professional Question and Answer Brochure, Healthcare Professional Checklist and Patient Alert Card. For key elements of the educational material see Annex 6.*

Squamous cell carcinoma Important identified risk	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.4 and 4.8* – Restricted medical prescription Additional risk minimisation measures: - *Educational material for healthcare professionals and patients. The educational material shall consist of Healthcare Professional Question and Answer Brochure, Healthcare Professional Checklist and Patient Alert Card. For key elements of the educational material see Annex 6.*

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 Voriconazole Stada.

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

There are no studies required for Voriconazole Stada.