Part VI: Summary of the risk management plan

Summary of risk management plan for Voriconazole 200 mg film-coated tablets (voriconazole)

This is a summary of the risk management plan (RMP) for Voriconazole 200 mg film-coated tablets (Voriconazole Denk). The RMP details important risks of Voriconazole Denk, how these risks can be minimised, and how more information will be obtained about Voriconazole Denk 's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Voriconazole Denk is authorised for (see SmPC for the full indication):

- 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.

Voriconazol Denk 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.

It contains voriconazole as the active substance and it is given by oral route of administration.

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

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

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*.

II.A List of important risks and missing information

Important risks of Voriconazole Denk 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 Voriconazole Denk. 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	• Phototoxicity • Squamous cell carcinoma (SCC)
Important potential risks	None
Missing information	None

II.B Summary of important risks

Phototoxicity	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 and 4.8; PL section 2 and 4 Prescription only medicine. Additional risk minimisation measures: Patient Alert Card.

Squamous cell carcinoma (SCC)	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 and 4.8; PL section 2 and 4

Squamous cell carcinoma (SCC)	
	Prescription only medicine. Additional risk minimisation measures: Patient Alert Card.

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 Denk.

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

There are no studies required for Voriconazole Denk.