Summary of risk management plan for [Voriconazole] 200 mg powder for solution for infusion

This is a summary of the risk management plan (RMP) for [Voriconazole] 200 mg powder for solution for infusion. The RMP details important risks of [Voriconazole] 200 mg powder for solution for infusion, how these risks can be minimised and how more information will be obtained about [Voriconazole] 200 mg powder for solution for infusion risks and uncertainties (missing information).

[Voriconazole] 200 mg powder for solution for infusion summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Voriconazole] 200 mg powder for solution for infusion should be used.

I. The medicine and what it is used for

[Voriconazole] 200 mg powder for solution for infusion is authorized for the treatment of invasive aspergillosis, candidaemia in non-neutropenic patients, fluconazole-resistant serious invasive *Candida* infections (including *C. krusei*) and serious fungal infections caused by *Scedosporium* spp. and *Fusarium* spp (see SmPC for the full indication).
It contains voriconazole as the active substance and it is as an intravenous infusion (not for bolus injection).

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

Important risks of [Voriconazole] 200 mg powder for solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about [Voriconazole] 200 mg powder for solution for infusion'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] 200 mg powder for solution for infusion, these measures are supplemented with additional risk minimization 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.*

If important information that may affect the safe use of [Voriconazole] 200 mg powder for solution for infusion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of [Voriconazole] 200 mg powder for solution for infusion 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] 200 mg powder for solution for infusion. 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).

Important identified risks	• Phototoxicity • Squamous cell carcinoma (SCC) • Hepatic toxicity • QTc prolongation • Visual events
Important potential risks	• Skin cancer (non-SCC) • Suicide-related events
Missing information	• Effects in pregnancy • Effects in paediatrics • Off-label use

II.B Summary of important risks

Important identified risk: Phototoxicity

Risk minimisation measures	*Routine Risk minimization measures:* SmPC sections 4.4 and 4.8, PL sections 2 and 4. Pack size: Each carton contains 1 vial. 25 mL clear Type I glass vial with a grey, chlorobutyl rubber stopper and aluminium cap with plastic red flip-off seal. *Additional risk minimization measures:* Educational materials for physicians and patients: • HCP Question and Answer Brochure • HCP Checklist • Patient Alert Card
Important identified risk: Squamous cell carcinoma	
Risk minimisation measures	*Routine Risk minimization measures:* SmPC sections 4.4 and 4.8, PL sections 2 and 4 Pack size: Each carton contains 1 vial.
	25 mL clear Type I glass vial with a grey, chlorobutyl rubber stopper and aluminium cap with plastic red flip-off seal. *Additional risk minimization measures:* Educational materials for physicians and patients: • HCP Question and Answer Brochure • HCP Checklist • Patient Alert Card
Important identified risk: Hepatic toxicity	
Risk minimisation measures	*Routine Risk minimization measures:* SmPC sections 4.4 and 4.8, PL sections 2 and 4 Pack size: Each carton contains 1 vial. 25 mL clear Type I glass vial with a grey, chlorobutyl rubber stopper and aluminium cap with plastic red flip-off seal. *Additional risk minimization measures:* Educational materials for physicians: • HCP Question and Answer Brochure • HCP Checklist

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] 200 mg powder for solution for infusion.

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

There are no studies required for [Voriconazole] 200 mg powder for solution for infusion.