Part VI: Summary of the risk management plan

Summary of risk management plan for Voriconazole Accord 50 mg film-coated tablets, Voriconazole Accord 200 mg film-coated tablets, Voriconazole Accord 200 mg powder for solution for infusion, Voriconazole Accordpharma 200 mg Powder for Solution for Infusion (Voriconazole)

This is a summary of the risk management plan (RMP) for Voriconazole Accord 50 mg film-coated tablets, Voriconazole Accord 200 mg film-coated tablets, Voriconazole Accord 200 mg powder for solution for infusion Voriconazole Accordpharma 200 mg Powder for Solution for Infusion. Throughout this summary product name to refer as Voriconazole Accord. The RMP details important risks of Voriconazole Accord, how these risks can be minimised, and how more information will be obtained about Voriconazole Accord's risks and uncertainties (missing information).

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

This summary of the RMP for Voriconazole Accord 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 Voriconazole's RMP.

I. The medicine and what it is used for

Voriconazole Accord is a broad spectrum, triazole antifungal agent and 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 Accord 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 and intravenous route.

Further information about the evaluation of Voriconazole Accord's benefits can be found in Voriconazole Accord'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/voriconazole-accord.

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

Important risks of Voriconazole Accord together with measures to minimise such risks and the proposed studies for learning more about Voriconazole 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 Accord, 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 during signal management activity, 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 Accord 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 Accord. 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)
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Important Identified Risk: **Phototoxicity**	
Risk minimisation measures	Routine risk minimisation measures: • SmPC Sections: 4.4 and 4.8 • PIL Sections: 4. • It is recommended that all patients, including paediatric patients, should avoid exposure to direct sunlight during voriconazole treatment and should use measures such as protective clothing and sunscreen with high sun protection factor (SPF), details are included in SmPC section 4.4.

	• If phototoxic reactions occur, the patient should be referred to a dermatologist and voriconazole discontinuation should be considered), details are included in SmPC section 4.4. • If voriconazole is continued despite the occurrence of phototoxicity-related lesions, dermatologic evaluation should be performed on a systematic and regular basis to allow early detection and management of premalignant lesions), details are included in SmPC section 4.4. • In children experiencing photoaging injuries such as lentigines or ephelides, sun avoidance and dermatologic follow-up are recommended even after treatment discontinuation), details are included in SmPC section 4.4. • Prescription only status of the product <u>Additional risk minimisation measures:</u> • Patient alert card
Important Identified Risk: **Squamous cell carcinoma (SCC)**	
Risk minimisation measures	<u>Routine risk minimisation measures</u>: • SmPC Sections: 4.4 and 4.8 • PIL Sections: 4. • Squamous cell carcinoma of the skin has been reported in patients, some of whom have reported prior phototoxic reactions. If phototoxic reactions occur multidisciplinary advice should be sought, Voriconazole Accord discontinuation and use of alternative antifungal agents should be considered and the patient should be referred to a dermatologist), details are included in SmPC section 4.4.

	• Voriconazole Accord should be discontinued if premalignant skin lesions or squamous cell carcinoma are identified), details are included in SmPC section 4.4. • Prescription only status of the product 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 Accord.

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

There are no other studies in post-authorisation development plan for Voriconazole Accord.