VORICONAZOL ACCORD (voriconazole) Healthcare Professional Checklist

Please complete this Checklist at each visit with your patient being treated with Voriconazole Accord (voriconazole). Each of the three sections includes important risk information followed by a series of check boxes to help in the management of your patient for whom you prescribed Voriconazole Accord.

A) Minimizing the Risk of Phototoxicity and Skin Squamous Cell Carcinoma

- Voriconazole Accord has been associated with phototoxicity and pseudoporphyria. It is recommended that all patients, including children, avoid exposure to direct sunlight during Voriconazole Accord treatment and use measures such as protective clothing and sufficient sunscreen with high sun protection factor (SPF).
- The frequency of phototoxicity reactions is higher in the paediatric population. As an evolution towards SCC has been reported, stringent measures for the photoprotection are warranted in this population of patients. In children experiencing photoaging injuries such as lentigines or ephelides, sun avoidance and dermatologic follow-up are recommended even after treatment discontinuation.
- Squamous cell carcinoma (SCC) of the skin has been reported in patients taking Voriconazole Accord, some of whom have reported prior phototoxic reactions.
- If phototoxic reactions occur, multidisciplinary advice (e.g., a consultation with a dermatologist) should be sought for the patient. Voriconazole Accord discontinuation and use of alternative antifungal agents should be considered.
- Dermatologic evaluation should be performed on a regular basis whenever Voriconazole Accord is continued, despite occurrence of phototoxicity-related lesions, to allow early detection and management of premalignant lesions.
- Voriconazole Accord should be discontinued if premalignant skin lesions or skin SCC are identified.
- SCC has been reported in relation with long-term Voriconazole Accord treatment. Treatment duration should be as short as possible. Long- term exposure (treatment or prophylaxis) greater than 180 days (6 months) requires careful assessment of the benefit risk balance and physicians should therefore consider the need to limit the exposure to Voriconazole Accord.
- For prophylaxis use, dose adjustments are not recommended in the case of lack of efficacy or treatment-related adverse events. In the case of treatment-related adverse events, discontinuation of voriconazole and use of alternative antifungal agents must be considered.

Refer to the Summary of Product Characteristics for full prescribing information.

Please review and answer the questions below for each patient receiving Voriconazole Accord:

☐ **Has your patient developed phototoxicity?** **YES** ☐ **NO** ☐

***If YES,* please refer to section 4.4 of the Summary of Product Characteristics (SmPC) for guidance.**

☐ **Have you arranged regular dermatologic evaluation for the patient if he/she presented with phototoxicity?** **YES** ☐ **NO** ☐

***If YES,* please refer to section 4.4 of the SmPC for further details. *If NO,* regular dermatologic evaluation should be arranged promptly. Please refer to section 4.4 of the SmPC for further details.**

☐ **In case of phototoxicity, did you consider discontinuing treatment with Voriconazole Accord?** **YES** ☐ **NO** ☐

***If YES*, please refer to section 4.4 of the SmPC for further advice.**

***If NO,* Voriconazole Accord discontinuation and use of alternative antifungal agents should be considered. Please refer to section 4.4 of the SmPC for further instruction.**

☐ **In case of premalignant skin lesions or SSC, did you discontinue treatment with Voriconazole Accord?** **YES** ☐ **NO** ☐

***If NO,* Voriconazole Accord should be discontinued. Please refer to section 4.4 of the SmPC for further advice.**

B) Important Information Regarding Voriconazole Accord and Liver Function Monitoring

- Patients receiving Voriconazole Accord must be carefully monitored for hepatic toxicity.
  - Clinical management should include laboratory evaluation of hepatic function (specifically AST and ALT) at the initiation of treatment with Voriconazole Accord and at least weekly for the first month of treatment. If there are no changes in these liver function tests (LFTs) after one month, monitoring frequency can be reduced to monthly.
  - If the LFTs become markedly elevated, Voriconazole Accord should be discontinued, unless the medical judgment of the risk-benefit balance of the treatment for the patient justifies continued use.
  - There are limited data on the safety of Voriconazole Accord in patients with abnormal LFTs (aspartate transaminase [AST], alanine transaminase [ALT], alkaline phosphatase [AP], or total bilirubin >5 times the upper limit of normal).
  - Voriconazole has been associated with elevations in LFTs and clinical signs of liver damage, such as jaundice, and must only be used in patients with severe hepatic impairment if the benefit outweighs the potential risk.
  - It is recommended that the standard loading dose regimens be used but that the maintenance dose be halved in patients with mild to moderate hepatic cirrhosis (Child-Pugh A and B) receiving voriconazole.
  - Voriconazole has not been studied in patients with severe chronic hepatic cirrhosis (Child-Pugh C).
  - For prophylaxis use, dose adjustments are not recommended in the case of lack of efficacy or treatment-related adverse events. In the case of treatment-related adverse events, discontinuation of voriconazole and use of alternative antifungal agents must be considered.

Please review and answer the questions below for each patient receiving Voriconazole Accord:

☐ **Have you recently checked liver function test (LFT) results for your patient?** **YES** ☐ **NO** ☐

***If YES,* use these results to closely monitor hepatic drug toxicity. Please refer to sections 4.2 and 4.4 of the Summary of Product Characteristics (SmPC) for guidance.**

☐ **Does your patient have hepatic cirrhosis?** **YES** ☐ **NO** ☐

***If YES,* dose adjustment is advised. Please refer to sections 4.2 and 4.4 of the SmPC for details.**

☐ **Have you arranged for routine monitoring of LFTs for your patient at least weekly for the first month of treatment while he/she is receiving treatment with Voriconazole Accord? *If YES,* please refer to sections 4.2 and 4.4 of the SmPC for further details. *If NO,* routine monitoring should be arranged promptly. Please refer to sections 4.2 and 4.4 of the SmPC for further details.** **YES** ☐ **NO** ☐

C) Discussion with Your Patient

Regarding phototoxicity and skin SCC

Have you discussed the risks of phototoxicity and skin SCC with Voriconazole Accord and the need for regular dermatological evaluation (if phototoxicity occurs)?	**YES**	☐	**NO**	☐
Have you discussed the need to avoid sunlight and sun exposure (including use of protective clothing and sufficient sunscreen with high sun protective factor [SPF]) during treatment with Voriconazole Accord?	**YES**	☐	**NO**	☐
Have you discussed the signs and symptoms of phototoxicity that warrant contacting the doctor immediately?	**YES**	☐	**NO**	☐
Have you given the patient a **Patient Alert Card** that was provided to you in the package?	**YES**	☐	**NO**	☐
Have you discussed with caregivers/parents of your paediatric patients, who experience photoaging injuries, the need to avoid all sun exposure and have follow-up dermatologic evaluations even after Voriconazole Accord treatment is discontinued?	**YES**	☐	**NO**	☐

Regarding hepatotoxicity

Have you discussed the risk of liver toxicity with Voriconazole Accord and the need for periodic monitoring of liver function?	**YES**	☐	**NO**	☐
Have you discussed the signs and symptoms of liver injury that warrant contacting the doctor immediately?	**YES**	☐	**NO**	☐

D) How do I report Adverse Reactions/Events?

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Medicines Authority Post-Licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR 1368, Malta, or at: http://www.medicinesauthority.gov.mt/adrportal.

Adverse events should also be reported to Accord by contacting Accord's Medical Information office at: +356 9985 6392 (tel), +356 2738 6222 (fax) or at malta@accord-healthcare.com.

Please retain the completed checklist in patient's medical record.

Please report any suspected adverse drug reactions related to Voriconazole Accord in the usual way.