VFEND® (voriconazole) Healthcare Professional Checklist

Please complete this Checklist at each visit with your patient being treated with VFEND® (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 VFEND.

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

- VFEND has been associated with phototoxicity and pseudoporphyria. It is recommended that all patients, including children, avoid intense or prolonged exposure to direct sunlight during VFEND treatment and use measures such as protective clothing and sufficient sunscreen with high sun protection factor (SPF).
- Squamous cell carcinoma (SCC) of the skin has been reported in patients taking VFEND, 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 .VFEND discontinuation should be considered.
- Dermatologic evaluation should be performed on a regular basis whenever VFEND is continued, despite occurrence of phototoxicity-related lesions to allow early detection and management of premalignant lesions.
- VFEND should be discontinued if premalignant skin lesions or skin SCC are identified.
- SCC has been reported in relation with long-term VFEND treatment. Treatment duration should be as short as possible and long-term treatment (greater than 6 months) should be considered only if the benefits outweigh the potential risks. Physicians therefore should consider the need to limit the exposure to VFEND only if the benefits outweigh the potential risks. Refer to the Summary of Product Characteristics for full prescribing and adverse event information.
- 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 VFEND:

☐ **Has your patient developed phototoxicity?** **YES☐ NO☐**
***If YES,* please refer to 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 the SmPC for further details.**
***If NO*, regular dermatologic evaluation should be arranged promptly. Please refer to the SmPC for further details.**

☐ **In case of phototoxicity, did you consider discontinuing treatment with VFEND?** **YES☐ NO☐**
***If YES*, please refer to the SmPC for further advice.**
If NO, VFEND discontinuation should be considered. Please refer to the SmPC for further instruction.

☐ **In case of premalignant skin lesions or SSC, did you discontinue treatment with VFEND?** **YES☐ NO☐**
***If NO*, VFEND should be discontinued. Please refer to the SmPC for further advice.**

B) Important Information Regarding VFEND and Liver Function Monitoring

- Patients receiving VFEND 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 VFEND 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, VFEND 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 VFEND in patients with abnormal LFTs (Aspartate transaminase [AST], alanine transaminase [ALT], alkaline phosphatase [AP], or total bilirubin >5 times the upper limit of normal).

- VFEND 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 VFEND.

- VFEND 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 VFEND:

☐ **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 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 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 VFEND?** ☐ ☐
YES NO
***If YES,* please refer to the SmPC for further details.**
***If NO*, routine monitoring should be arranged promptly. Please refer to the SmPC for further details.**

C) Discussion with Your Patient

Regarding phototoxicity and skin SCC

Have you discussed the risks of phototoxicity and skin SCC with VFEND 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 VFEND? ☐ ☐ **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** ☐

Regarding hepatotoxicity

Have you discussed the risk of liver toxicity with VFEND 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** ☐