This document has been approved by Saudi Food and Drug Authority (SFDA).

Healthcare Professional Checklist

VECANZOL® (voriconazole)

Please complete this checklist for each visit with your patient being treated with VECANZOL® (Voriconazole). Each of the three sections includes important safety information followed by a serious of check boxes to help in the management of your patient for whom you prescribed VECANZOL®.

1.0- Sep 2024

www.mspharma.com

MS pharma

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

• VECANZOL® has been associated with phototoxicity and pseudoporphyria. It is recommended that all patients, including children, avoid exposure to direct sunlight during VECANZOL® 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 VECANZOL®, 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. VECANZOL® discontinuation and use of alternative antifungal agents should be considered.

• Dermatologic evaluation should be performed on a regular basis whenever VECANZOL® is continued, despite occurrence of phototoxicity-related lesions, to allow early detection and management of premalignant lesions.

• VECANZOL® should be discontinued if premalignant skin lesions o r skin SCC are identified.

• SCC has been reported in relation with long-term VECANZOL® 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 consider the need to limit the exposure to VECANZOL®.

• For prophylaxis use dose adjustment 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 (SPC) for full prescribing information.

Please review and answer the questions below for each patient receiving VECANZOL®:

Has your patient developed phototoxicity? If YES, please refer to the Summary of Product Characteristics (SPC) for guidance.	YES ☐ NO ☐
Have you arranged regular dermatologic evaluation for the patient if he/she presented with phototoxicity? If YES, please refer to the SPC for further details. If NO, regular dermatologic evaluation should be arranged promptly. Please refer to the SPC for further details.	YES ☐ NO ☐
In case of phototoxicity, did you consider discontinuing treatment with VECANZOL®? If YES, please refer to the SPC for further advice. If NO, VECANZOL® discontinuation should be considered.	YES ☐ NO ☐

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

B) Important Information Regarding VECANZOL® and Liver Function Monitoring
Patients receiving VECANZOL® must be carefully monitored for hepatic toxicity.

• Clinical management should include laboratory evaluation of hepatic function (specially AST and ALT) at the initiation of treatment with VECANZOL® and at least weekly for the first month of treatment. If there is no change in these liver function tests (LFTs) after one month, monitoring frequency can be reduced to monthly.
• If the LFTs become markedly elevated, VECANZOL® 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 VECANZOL® in patients with abnormal LFTs (aspartate transaminase [AST], alanine transaminase [ALT], alkaline phosphatase [AP], or total bilirubin >5 times the upper limit of normal).
• VECANZOL® 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 VECANZOL®.
• VECANZOL® has not been studied in patients with severe chronic hepatic cirrhosis (Child Pugh C).
• For prophylaxis use dose adjustment 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 VECANZOL® and use of alternative antifungal agents must be considered.

Please review and answer the questions below for each patient receiving VECANZOL®:

Have you recently checked liver function test (LFT) results for your patient? If YES, use these results to closely monitor hepatic drug toxicity. Please refer to the Summary of Product Characteristics (SPC) for guidance.	YES ☐ NO ☐
Does your patient have hepatic cirrhosis? If YES, dose adjustment is advised. Please refer to the SPC for details.	YES ☐ NO ☐
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 VECANZOL®? If YES, please refer to the SPC for further details.	YES ☐ NO ☐

If NO, routine monitoring should be arranged promptly. Please refer to the SPC for further details	

C) Discussion with Your Patient

Regarding phototoxicity and skin SCC

Have you discussed the risks of phototoxicity and skin SCC with VECANZOL® 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 SPF) during VECANZOL® treatment?	YES ☐ NO ☐
Have you discussed the signs and symptoms of photoxicity 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 followup dermatologic evaluations even after VECANZOL® treatment is discontinued?	YES ☐ NO ☐

Regarding hepatotoxicity

Have you discussed the risk of liver toxicity with VECANZOL® 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 ☐

Call for reporting:

Report suspected adverse drug reactions associated with Fovlya® (Aflibercept) by contacting:

- **Pharmacovigilance Department at MS Pharma:**
  - **Email:** pharmacovigilance@mspharma.com
  - **Website:** www.mspharma.com
  - **Phone No:** + 966112790122 Ext. 6013

- **The National Pharmacovigilance Center (NPC): (Saudi food and drug authority)**
  - **Email:** npc.drug@sfda.gov.sa
  - **Call Center:** 19999
  - **Website:** https://ade.sfda.gov.sa/
  - **QR Code:**