

# Vorican®

## Voriconazole

### VORICAN® (voriconazole) Healthcare Professional Checklist

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

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

- VORICAN has been associated with phototoxicity and pseudoporphyria. It is recommended that all patients, including children, avoid exposure to direct sunlight during VORICAN 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 VORICAN, 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. VORICAN discontinuation and use of alternative antifungal agents should be considered.
- Dermatologic evaluation should be performed on a regular basis whenever VORICAN is continued, despite occurrence of phototoxicity-related lesions, to allow early detection and management of premalignant lesions.
- VORICAN should be discontinued if premalignant skin lesions or skin SCC are identified.
- SCC has been reported in relation with long-term VORICAN 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 VORICAN.
- 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 VORICAN:

<p><b>Has your patient developed phototoxicity?</b> If YES, please refer to the Summary of Product Characteristics (SmPC) for guidance.</p>	YES <input type="checkbox"/> NO <input type="checkbox"/>
<p><b>Have you arranged regular dermatologic evaluation for the patient if he/she presented with phototoxicity?</b> 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.</p>	YES <input type="checkbox"/> NO <input type="checkbox"/>
<p><b>In case of phototoxicity, did you consider discontinuing treatment with VORICAN?</b> If YES, please refer to the SmPC for further advice. If NO, VORICAN discontinuation should be considered. Please refer to the SmPC for further instruction.</p>	YES <input type="checkbox"/> NO <input type="checkbox"/>
<p><b>In case of premalignant skin lesions or SSC, did you discontinue treatment with VORICAN?</b> If NO, VORICAN should be discontinued. Please refer to the SmPC for further advice.</p>	YES <input type="checkbox"/> NO <input type="checkbox"/>

#### B) Important Information Regarding VORICAN and Liver Function Monitoring

Patients receiving VORICAN 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 VORICAN 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, VORICAN 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 VORICAN in patients with abnormal LFTs (aspartate transaminase [AST], alanine transaminase [ALT], alkaline phosphatase [AP], or total bilirubin >5 times the upper limit of normal).
- VORICAN 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 VORICAN.
- VORICAN 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 VORICAN and use of alternative antifungal agents must be considered.

**Please review and answer the questions below for each patient receiving VORICAN:**

<p><b>Have you recently checked liver function test (LFT) results for your patient?</b>  <i>If YES, use these results to closely monitor hepatic drug toxicity. Please refer to the Summary of Product Characteristics (SmPC) for guidance.</i></p>	<p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>
<p><b>Does your patient have hepatic cirrhosis?</b>  <i>If YES, dose adjustment is advised. Please refer to the SmPC for details.</i></p>	<p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>
<p><b>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 VORICAN?</b>  <i>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.</i></p>	<p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>

**C) Discussion with Your Patient**

**Regarding phototoxicity and skin SCC**

<p>Have you discussed the risks of phototoxicity and skin SCC with VORICAN and the need for regular dermatological evaluation (if phototoxicity occurs)?</p>	<p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>
<p>Have you discussed the need to avoid sunlight and sun exposure (including use of protective clothing and sufficient sunscreen with high SPF) during VORICAN treatment?</p>	<p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>
<p>Have you discussed the signs and symptoms of phototoxicity that warrant contacting the doctor immediately?</p>	<p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>
<p>Have you given the patient a Patient Alert Card that was provided to you in the package?</p>	<p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>
<p>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 VORICAN treatment is discontinued?</p>	<p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>

**Regarding hepatotoxicity**

<p>Have you discussed the risk of liver toxicity with VORICAN and the need for periodic monitoring of liver function?</p>	<p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>
<p>Have you discussed the signs and symptoms of liver injury that warrant contacting the doctor immediately?</p>	<p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>

**To Report any Adverse Drug Reaction or Concerns Please call:**

**• SAJA Pharmaceuticals Co. Ltd.**

P.O. Box: 42600, Jeddah 21551, KSA

Tel: + 6066667 12 966

Website: sajapharma.com

**• National Pharmacovigilance and Drug Safety Center**

SFDA call center: 19999

E-Mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa>