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IMPORTANT SAFETY INFORMATION

Direct healthcare professional communication on the potential risk of squamous cell carcinoma (SCC) associated with long term VFEND therapy

Summary

- A small number of cases of squamous cell carcinoma (SCC) of the skin have been identified during long-term treatment in patients with phototoxicity and additional risk factors, including immunosuppression.
- The contribution of voriconazole to the development of SCC has not been established.
- The use of protective clothing, UV skin protection with adequate sunscreen and the avoidance of intense or prolonged exposure to sunlight is emphasized.
- Treatment duration should be as short as possible taking into account the patient's clinical and mycological response.

The information in this letter has been endorsed by The European Medicines Agency and the Irish Medicines Board (IMB) and the Marketing Authorisation Holder.

Further information on the safety concern

Published observational case-series reviews and individual case reports in the literature, as well as spontaneous post-marketing reports, have identified a small number of cases of squamous cell carcinoma (SCC) of the skin in patients with phototoxicity receiving long-term voriconazole (exceeding 180 days in the majority of cases). Risk factors for the development of cutaneous SCC in these patients included skin phototype, cumulative exposure to sunlight (ultraviolet radiation), and immunosuppression (especially chronic immunosuppression secondary to chemotherapy or organ transplantation). The contribution of voriconazole to the development of SCC has not been established. To minimize the risk for the development of phototoxicity in patients receiving voriconazole, it is emphasized to avoid direct sunlight exposure and the use of protective clothing and UV skin protection with adequate sunscreen.

Voriconazole should be prescribed in accordance with the treatment indications within the approved SmPC (see Annex). Treatment duration should be as short as possible and long-term treatment with voriconazole (greater than 6 months) should be considered only if the benefits outweigh the potential risks.

The additional information has also been reflected in the User Package Leaflet.

Reporting

If you become aware of any suspected adverse reactions in association with the use of Vfend, please report the event to the Pfizer Drug Safety group at Pfizer Limited, Walton Oaks, Dorking Road, Walton on the Hill, Surrey KT20 7NS United Kingdom, free phone 1800 633 363 or to the Irish Medicines Board in the usual way (www.imb.ie).

Further information
If you have a medical inquiry regarding Vfend, please contact Pfizer Medical Information on 1800 633 363.

Sincerely,

Dr Declan O'Callaghan
Director of Medical Affairs
Pfizer Healthcare Ireland.

APPENDIX

Revisions made to Sections 4.2 and 4.4 of the Vfend SmPC:

4.2 Posology and method of administration

Treatment duration should be as short as possible depending on the patients' clinical and mycological response.

The duration of treatment with the intravenous formulation should be no longer than 6 months. See section 5.3 (preclinical safety data). For voriconazole in general, long term treatment greater than 6 months requires careful assessment of the benefit-risk balance. See section 4.4 Special warnings and precautions for use (Dermatological adverse events), section 5.1 Pharmacodynamic properties (Duration of treatment).

4.4 Special warnings and special precautions for use

Duration of IV treatment:
The duration of treatment with the intravenous formulation should be no longer than 6 months. See section 5.3 (Preclinical safety data).

Dermatological adverse events:

In addition VFEND has been associated with phototoxicity and pseudoporphyria. It is recommended that patients avoid intense or prolonged exposure to direct sunlight during VFEND treatment and use measures such as protective clothing and sunscreen when appropriate. In patients with phototoxicity and additional risk factors, including immunosuppression, squamous cell carcinoma of the skin has been reported during long-term therapy. Physicians should therefore consider the need to limit the exposure to VFEND (see Section 4.2 (Posology and method of administration) and Section 5.1 Pharmacodynamic properties (Duration of treatment). If a patient develops a skin lesion consistent with squamous cell carcinoma, VFEND discontinuation should be considered.

Text added to the Vfend User Package Leaflet:

Take special care with VFEND:

- to avoid sunlight and sun exposure while being treated. It is important to cover sun exposed areas of skin and use sunscreen, as an increased sensitivity of skin to the sun's UV rays can occur.

While being treated with VFEND:

- tell your doctor immediately if you develop a severe skin rash or blisters.
- avoid sunlight and sun exposure while being treated with VFEND. Cover sun exposed areas of skin and use sunscreen, as an increased sensitivity of skin to the sun's UV rays can occur.