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Worldwide Biopharmaceutical Businesses

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Voriconazole (Vfend®): risk of phototoxicity, skin squamous cell carcinoma and liver toxicity – introducing tools to manage these risks.

Dear Healthcare Professional

Pfizer, in collaboration with the European Medicines Agency (EMA) and MHRA would like to inform you of the following:

Summary

- Voriconazole is associated with a risk of phototoxicity and skin squamous cell carcinoma (SCC). It is therefore important to adhere to the advice on the precautions against phototoxic reactions and monitoring for SCC given in the product information. If phototoxic reactions occur, refer the patient to consult a dermatologist and consider stopping voriconazole treatment
- If voriconazole treatment is continued despite a phototoxic reaction, the skin should be checked frequently and thoroughly to detect and manage pre-cancerous lesions as early as possible. Stop voriconazole treatment if pre-cancerous skin lesions or SSC are identified
- Voriconazole is also associated with a risk of liver toxicity. Advice on monitoring liver function in the product information has been revised. It is also important to adhere to this advice.

Further information

Voriconazole is an antifungal medicine used to treat adults and children over the age of two years with worsening, possibly life-threatening fungal infections.

A risk minimization programme has been developed to help manage the aforementioned risks in all patients, including children, taking voriconazole. This programme includes the following documents which are enclosed in this letter:

1. Healthcare Professionals' Q&A Brochure:
   - Explains the risks of phototoxicity, skin SCC and liver toxicity associated with voriconazole
   - Recommends how to monitor and manage these risks
   - Reminds to use the HCP Checklist and Patient Alert Card, and how to obtain additional copies

2. Healthcare Professionals' Checklist:
   - Reminds of the risks of phototoxicity, skin SCC and liver toxicity associated with voriconazole and how to evaluate and manage these risks
   - Reminds to discuss with the patient/care-giver:
     - the risks associated with voriconazole
     - which signs and symptoms to watch out for

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Registered Office: Ramsgate Road
Sandwich, Kent CT13 9NJ, UK

- how and when to seek medical attention
- the importance of using the Patient Alert Card

3. Patient Alert Card:
   - Reminds patients of the risk of phototoxicity and skin SCC associated with voriconazole
   - Reminds patients how to minimize the risk of phototoxicity and skin SCC (eg, by avoiding prolonged exposure to direct sunlight, using effective sunscreen and wearing protective clothing)
   - Reminds patients when and how to report signs and symptoms of phototoxicity and skin SSC

Call for reporting
Please report suspected adverse reactions with this medicine to the MHRA through the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard. Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: "FREEPOST YELLOW CARD"
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- Or by electronic download through the Yellow Card section of the MHRA website

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Company contact
Please report any adverse reactions in association with the use of voriconazole to Pfizer Pharmacovigilance, Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey KT20 7NS Email: GBR.AEReporting@Pfizer.com Fax: 0845 300 8032 Web: www.pfizer.co.uk

If you need additional information or you would like to order more copies of the above mentioned materials, please contact Pfizer Medical Information at 01304 616161
You can find the voriconazole summary of product characteristics on the EMA website at http://tiny.cc/p7ojax.

Sincerely,

Seema Patel MPharm, MRPharmS
Medical Director, UK Established Pharma Business
Pfizer UK