



Worldwide Biopharmaceutical Businesses

September 2014

Voriconazole (Vfend®): Updated risk minimisation materials

Dear healthcare professional,

The enclosed risk minimisation materials have been updated to align with recent changes to the voriconazole (Vfend®) summary of product characteristics (SmPC).

Voriconazole is an antifungal medicine used to treat adults and children over the age of two years with worsening, possibly life-threatening fungal infections and for prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem cell transplant recipients (HSCT). You can find the updated voriconazole summary of product characteristics on the electronic Medicines Compendium website, www.medicines.org.uk

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 precancerous lesions as early as possible. Stop voriconazole treatment if precancerous 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.

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 risk minimisation materials, please contact Pfizer Medical Information at 01304 616161.

Sincerely,

A handwritten signature in black ink, appearing to be 'Seema Patel', written in a cursive style.

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