

MSD  
Hertford Road  
Hoddesdon  
Hertfordshire EN11 9BU  
UK  
Telephone Hoddesdon +44 (0)1992 467272  
Facsimile +44 (0)1992 468175



## **Direct Healthcare Professional Communication**

6<sup>th</sup> July 2016

### **NOXAFIL (posaconazole) tablet and oral suspension not interchangeable**

Dear Healthcare Professional,

Merck Sharp & Dohme Limited (MSD) in agreement with the European Medicines Agency and the Medicines & Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

#### ***Summary***

- Posaconazole tablets and oral suspension are not interchangeable
- Substitution of the tablets for the oral suspension, or vice versa, can result in inadvertent overdosing or underdosing, and the risk of serious adverse drug reactions or lack of efficacy
- Prescribers should specify the dosage form for posaconazole on each prescription and pharmacists should ensure the correct oral form is dispensed to patients

#### ***Background on the safety concern***

Posaconazole is a broad-spectrum triazole antifungal for the treatment of fungal infections and prophylaxis of invasive fungal infections (IFIs).

Posaconazole is available as an oral suspension (40 mg/mL), tablets (100 mg), and concentrate for solution for infusion (300 mg). The labelled oral dosage of posaconazole is:

- Tablet: 300 mg /day (following a loading dose on Day 1 of 600 mg/day)
- Oral suspension: 600-800 mg/day

Medication errors related to substitutions of Noxafil tablets and oral suspension have been reported. Inadvertent switching from oral solution to tablets has resulted in cases of dose-related toxicity, while switching from tablets to oral solution has resulted in under-dosing and lack of efficacy. The posaconazole SmPC and Package Leaflet are being updated to clarify that the oral solution cannot be directly substituted for the oral tablet, or vice versa. The outer cartons of the EU oral forms are being revised to further differentiate between the tablet and oral suspension forms, and will include a warning statement on non-interchangeability of the two.

## ***Call for reporting***

Healthcare providers and patients are encouraged to report adverse events in patients taking NOXAFIL to the MHRA through the Yellow Card Scheme online at <http://yellowcard.mhra.gov.uk/>.

This letter is not intended as a complete description of the benefits and risks related to the use of NOXAFIL. Please refer to the Summary of Product Characteristics for full prescribing advice.

## ***Company contact point***

If you have any questions, or if you require any further information, please contact the Medical Information Department of:

Merck Sharp & Dohme Limited,  
Hertford Road,  
Hoddesdon,  
Hertfordshire EN11 9BU  
United Kingdom

Telephone: 01992 467272

Email: [medicalinformationuk@merck.com](mailto:medicalinformationuk@merck.com)

Yours sincerely



Dr Mark Toms  
UK Medical Director  
Merck Sharp & Dohme Limited