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MSD

Direct Healthcare Professional Communication

20th 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 Health Products Regulatory Authority (HPRA) 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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: http://www.hpra.ie/; email: medsafety@hpra.ie.

Suspected adverse reactions can also be reported to MSD at 01 2998700.

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 require additional information regarding the use of Noxafil, please contact MSD by calling 01 2998700.

Yours sincerely,

Dr. Colm Galligan
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Medical Director