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## Direct Healthcare Professional Communication

### **NOXAFIL® (posaconazole) new Gastro-Resistant Powder and Solvent for Oral Suspension not interchangeable with existing Oral Suspension including generics.**

Dear Healthcare professional,

Merck Sharp & Dohme (UK) Limited (MSD) in agreement with the MHRA would like to inform you of the following:

#### **Summary**

- A new formulation of Noxafil, gastro-resistant powder and solvent for oral suspension (PFS) has been approved for use in children 2 years of age and older
- The newly available Noxafil PFS and the existing oral suspension (OS) formulation including generics are not interchangeable
- Substitution between the two formulations can potentially result in over or underdosing, and risks of serious adverse drug reactions or lack of efficacy
- Prescribers should always specify the formulation and dosage for posaconazole on each prescription
- Pharmacists should ensure correct formulation and dosing are dispensed to patients.
- As a reminder, posaconazole tablets and oral suspension (OS) are not interchangeable.

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

Posaconazole (POS) is a broad-spectrum tri-azole antifungal compound indicated for the treatment of fungal infections and the prophylaxis of invasive fungal infections (IFIs).

Posaconazole is available in the following formulations:

- oral suspension (OS, 40 mg/mL) for adults,
- gastro-resistant tablet (100 mg) for adults and paediatric population from 2 years old (weighing more than 40 kg),
- gastro-resistant powder and solvent for oral suspension (PFS, 300 mg powder sachet) for paediatric population from 2 years old,
- concentrate for solution for infusion (IV, 18 mg/mL) for adults and paediatric population from 2 years old.

The oral suspension (OS) is not interchangeable with gastro-resistant powder and solvent for oral suspension (PFS) due to the differences between these formulations in dosages, dosing schedules,

and plasma drug concentrations. The dose for PFS also differs from the dose of IV formulation in paediatric patients.

Medication errors related to substitutions between Noxafil and generics OS formulation and Noxafil PFS could result in dosing errors potentially leading to adverse events in cases of overdosing or lack of efficacy in cases of under-dosing.

Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed. These can be found at [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc)

### **Call for reporting**

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website <https://yellowcard.mhra.gov.uk>
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

Adverse reactions should also be reported to the relevant company [see below for company contact details]. Please report the product name and batch details.

### **Company contact point**

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

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Yours sincerely,

*Benjamin David*

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Reason: Reviewed  
Date: Aug 20, 2024 12:20 GMT+1*

Dr Benjamin David  
Director of Medical Affairs UK: General and Speciality Medicine, MSD UK

On behalf of Christoph Hartmann, Country Medical Director, MSD UK