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15th August 2016

NOXAFIL (posaconazole) tablet fully funded from 1st September 2016

Dear Healthcare Professional,

This letter is to inform you that the tablet formulation of NOXAFIL (posaconazole) will be fully funded from the 1st September 2016.
Posaconazole 100 mg modified-release tablets will be listed on the Pharmaceutical Schedule subject to the same Special Authority criteria and hospital restrictions that currently apply to posaconazole oral suspension 40 mg per ml.
MSD NZ also wishes to inform you of the following safety update:

NOXAFIL (posaconazole) tablet and oral suspension not interchangeable

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[1].

Orally, posaconazole is available as a suspension (40 mg/mL) and tablets (100 mg).

The labelled oral dosage of posaconazole is:

- Tablet: 300 mg /day (following a loading dose on Day 1 of 600 mg/day) (Pharmacode 2490811)
- Oral suspension: 600-800 mg/day (Pharmacode 2366266)

Medication errors related to substitutions of Noxafil tablets and oral suspension have been reported. Inadvertent switching from oral suspension to tablets has resulted in cases of dose-related toxicity, while switching from tablets to oral suspension has resulted in under-dosing and lack of efficacy. The posaconazole datasheet and CMI have been updated to clarify that the oral solution cannot be directly substituted for the oral tablet, or vice versa. The outer cartons of the 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 either MSD at DPOC.australia@merck.com or CARM at https://nzphvc.otago.ac.nz/reporting/ or nzphvc@otago.ac.nz.

Please refer to the abbreviated prescribing information on the back of this letter, for full prescribing information please visit www.medsafe.govt.nz.

Kind regards,
Danielle Street

Brand Manager, MSD NZ

References: 1. NOXAFIL Data Sheet, available at www.medsafe.govt.nz

NOXAFIL® (40 mg/mL posaconazole) Oral Suspension.
NOXAFIL® Modified Release Tablets 100 mg.
INDICATIONS: Treatment of invasive fungal infections (IFI) in patients ≥ 18 years: Aspergillosis refractory to or in patients intolerant of amphotericin B, itraconazole or voriconazole; Oesophageal candidiasis or candidaemia refractory to or in patients intolerant of amphotericin B, fluconazole or itraconazole; Fusariosis, Zygomycosis, Cryptococcosis, Chromoblastomycosis, Mycetoma refractory to or in patients intolerant of other therapy. Coccidioidomycosis. IFI prophylaxis in patients ≥ 13 years, incl. patients with prolonged neutropenia or haematopoietic stem cell transplant (HSCT) recipients. Treatment of oropharyngeal candidiasis (OPC) in adults including those with disease refractory (rOPC) to itraconazole and fluconazole (oral suspension only). **CONTRAINDICATIONS:** hypersensitivity to components or to posaconazole; coadministration with ergot alkaloids (ergotamine, dihydroergotamine), HMG-CoA reductase inhibitors primarily metabolised through CYP3A4, terfenadine, astemizole, cisapride, pimozide and quinidine. **PRECAUTIONS**: Hypersensitivity, hepatic toxicity; QT prolongation; fertility effects, use in pregnancy (Cat B3), lactation, paediatric and elderly patient use; effects on adrenal steroid hormones, drug interactions. **ADVERSE REACTIONS**: **Serious**: Dizziness, altered concentration of other drugs, fatigue, headache, cardio-respiratory arrest, ventricular hypertrophy, convulsions, anaemia, abdominal pain. **Common**: Anorexia, nausea, asthenia, fever, headache, confusion, tremor, paraesthesia, abdominal distension, pain, diarrhoea, raised liver function tests, others, see full Data Sheet. **DOSE: Oral Suspension:** Shake well before use. Administer with food (or nutritional supplement in patients who cannot tolerate food), to enhance exposure. IFI - Refractory/intolerant patients: 400mg (10mL) twice daily with a meal or nutritional supplement. Further dose division to 200mg (5mL) four times daily is recommended for patients with limited oral intake. IFI – Prophylaxis: 200mg (5mL) three times daily. OPC: Loading dose 200mg (5mL) once a day on first day, then 100mg (2.5mL) once a day for 13 days. rOPC: 400mg (10mL) twice daily. **Modified Release Tablets:** Can be taken without regard to food intake. Swallow tablets whole. Refractory IFI/Intolerant patients with IFI and Prophylaxis of IFI: Loading dose of 300 mg (three 100 mg tablets) twice a day on the first day, then 300 mg (three 100 mg tablets) once a day thereafter.
NOXAFIL® is a prescription only medicine. Marketed by Merck Sharp & Dohme (NZ) Limited, Newmarket, Auckland. AINF-1191672-0000. First issued July 2016. TAPS DA1634MW

Based on approved Data Sheet prepared 16 October 2015, available at www.medsafe.govt.nz.