16 September 2021
EMA/CHMP/508764/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Noxafil

posaconazole

On 16 September 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Noxafil. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V..

The CHMP adopted a change to the existing indication for Noxafil gastroresistant tablet and concentrate for solution for infusion, to primary treatment of invasive aspergillosis in adults, as follows:[2]

> Invasive aspergillosis ~~in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products~~

For information, the full indications for Noxafil will be as follows:

> Noxafil concentrate for solution for infusion is indicated for use in the treatment of the following fungal infections in adults (see section 5.1):

- Invasive aspergillosis;
- Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B;
- Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole;
- Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products.

> Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] Removed text as strikethrough

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Noxafil concentrate for solution for infusion is also indicated for prophylaxis of invasive fungal infections in the following patients:

- Patients receiving remission-induction chemotherapy for acute myelogenous leukaemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high-risk of developing invasive fungal infections;
- Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease (GVHD) and who are at high-risk of developing invasive fungal infections.

Please refer to the Summary of Product Characteristics of Noxafil oral suspension for use in oropharyngeal candidiasis.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.