29 January 2026
EMADOC-1700519818-2632880
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Noxafil

posaconazole

On 29 January 2026, 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 an extension to an existing indication for Noxafil gastro-resistant tablets, as follows:[2]

> Noxafil gastro-resistant tablets are indicated for use in the treatment of the following **invasive** fungal infections in adults **and paediatric patients from 2 years of age weighing more than 40 kg** (see sections 4.2 and 5.1):
>
> - Invasive aspergillosis;
>
> ~~Noxafil gastro-resistant tablets are indicated for use in the treatment of the following fungal infections in paediatric patients from 2 years of age weighing more than 40 kg and adults (see sections 4.2 and 5.1):~~
>
> - ~~Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products;~~
> - 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] New text in bold, removed text as strikethrough

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Noxafil gastro-resistant tablets are also indicated for prophylaxis of invasive fungal infections in ~~the following~~ **adults and** paediatric patients from 2 years of age weighing more than 40 kg ~~and adults~~ (see section ~~4.2 and~~ 5.1):

- 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 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.

The CHMP adopted an extension to an existing indication for Noxafil concentrate for solution for infusion, as follows: [2]

~~Noxafil concentrate for solution for infusion is indicated for use in the treatment of the following fungal infections in adults (see sections 4.2 and 5.1):~~

~~- Invasive aspergillosis~~

Noxafil concentrate for solution for infusion is indicated for use in the treatment of the following **invasive** fungal infections in adults and paediatric patients from 2 years of age (see sections 4.2 and 5.1):

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

Noxafil concentrate for solution for infusion is also indicated for prophylaxis of invasive fungal infections in ~~the following~~ adult**s** and paediatric patients from 2 years of age (see section ~~4.2 and~~ 5.1):

- 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 **adults with** oropharyngeal candidiasis.

The CHMP adopted an extension to an existing indication for Noxafil gastro-resistant powder and solvent for oral suspension, as follows:[2]

> Noxafil gastro-resistant powder and solvent for oral suspension is indicated for use in the treatment of the following **invasive** fungal infections in paediatric patients from 2 years of age (see sections 4.2 and 5.1):
>
> - Invasive aspergillosis; ~~in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products;~~
> - 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.
>
> Noxafil gastro-resistant powder and solvent for oral suspension is also indicated for prophylaxis of invasive fungal infections in the following paediatric patients from 2 years of age:
>
> - 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.

The indications for the Noxafil oral suspension remain unchanged and are available in section 4.1 of the summary of product characteristics (SmPC).

Detailed recommendations for the use of this product will be described in the updated SmPC, which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.