EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 November 2021
EMA/CHMP/598957/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Noxafil

posaconazole

On 11 November 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 has adopted an extension to the existing indications for Noxafil gastro-resistant tablets as follows:[1]

Noxafil gastro-resistant tablets are indicated for use in the treatment of the following fungal infections in adults (see section**s 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] New text as bold

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

The CHMP has also adopted an extension to the existing indications 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 section**s 4.2 and** 5.1):

- Invasive aspergillosis

Noxafil concentrate for solution for infusion is indicated for use in the treatment of the following fungal infections in adult 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 and paediatric** patients **from 2 years of age (see sections 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.

The CHMP also approved a new pharmaceutical form (gastro-resistant powder and solvent for oral suspension) for the paediatric population with the following indications:

[2] New text as bold

Noxafil gastro-resistant powder and solvent for oral suspension is indicated for use in the treatment of the following 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 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;
- Haematopoietic 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.

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.