



29 May 2019
EMA/CHMP/275501/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Posaconazole AHCL

posaconazole

On 29 May 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Posaconazole AHCL, intended for the treatment and prevention of fungal infections.

The applicant for this medicinal product is Accord Healthcare S.L.U.

Posaconazole AHCL will be available as a 40 mg/ml oral suspension. The active substance of Posaconazole AHCL is posaconazole, a triazole antimycotic (ATC code: J02AC04) that inhibits the enzyme lanosterol 14 α -demethylase (CYP51), which catalyses an essential step in ergosterol biosynthesis.

Posaconazole AHCL is a generic of Noxafil, which has been authorised in the EU since 25 October 2005. Studies have demonstrated the satisfactory quality of Posaconazole AHCL, and its bioequivalence to the reference product Noxafil. A question and answer document on generic medicines can be found [here](#).

The full indication is:

“Posaconazole AHCL is indicated for treatment of the following fungal infections in adults:

- 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.
- Oropharyngeal candidiasis: as first-line therapy in patients who have severe disease or are immunocompromised, in whom response to topical therapy is expected to be poor.

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



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.

Posaconazole AHCL is also indicated for prophylaxis of invasive fungal infections in the following patients:

- Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (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.”

It is proposed that Posaconazole AHCL be prescribed by physicians experienced in the management of fungal infections or in the supportive care of high risk patients for which posaconazole is indicated as prophylaxis.

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