14 December 2023
EMA/CHMP/559550/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion (post authorisation)

Fexinidazole Winthrop

fexinidazole

On 14 December 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion in accordance with Article 58 of Regulation (EC) No 726/2004[1], recommending a change to the product information for the medicinal product Fexinidazole Winthrop. The change for this medicinal product has been requested by Sanofi Winthrop Industrie.

The CHMP adopted an extension to an existing indication to include treatment of trypanosomiasis caused by *Trypanosoma brucei rhodesiense*. For information, the full indication will be as follows:[2]

> Fexinidazole Winthrop is indicated for the treatment of both first-stage (haemo-lymphatic) and second-stage (meningo-encephalitic) of human African trypanosomiasis (HAT) due to *Trypanosoma brucei gambiense* (g-HAT) and *Trypanosoma brucei rhodesiense* (r-HAT) in adults and children ≥ 6 years old and weighing ≥ 20 kg. Fexinidazole should be used in line with official recommendations (see section 4.4).

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).

Fexinidazole Winthrop is intended exclusively for markets outside the European Union.

[1] Scientific opinion in accordance with Article 58 of (EC) No Regulation 726/2004 in the context of cooperation with the World Health Organisation (WHO)
[2] New text in bold

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