



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 November 2018
EMA/791484/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion

Fexinidazole Winthrop

fexinidazole

On 15 November 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion in accordance with Article 58 of Regulation (EC) No 726/2004¹ for the medicinal product Fexinidazole Winthrop, intended for the treatment of human African trypanosomiasis (HAT) due to *Trypanosoma brucei gambiense*. This medicinal product has been developed by DNDi and sanofi-aventis groupe.

Fexinidazole Winthrop will be available as 600-mg tablets. The active substance of Fexinidazole Winthrop is fexinidazole, a nitro-imidazole derivative that generates reactive amines that exert indirect toxic and mutagenic effects on the trypanosomes.

Fexinidazole Winthrop has been showed to be effective at curing the disease (measured as the number of patients having no evidence of trypanosomes in any body fluid, not requiring rescue medication and having a cerebrospinal fluid white blood cell count ≤ 20 cells/ μ L). However, patients with more severe central nervous system involvement are deemed at higher risk of failing treatment with fexinidazole. The most common side effects are vomiting, nausea, headache, insomnia, asthenia, dizziness and tremor.

The full indication is:

“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* in adults and children ≥ 6 years old and weighing ≥ 20 kg.

Fexinidazole should be used in line with official recommendations.”

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).

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)

