24 February 2026
EMA/48340/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1]

Acoziborole Winthrop

acoziborole

On 24 February 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, in accordance with Article 58 of Regulation (EC) No 726/2004[2] for the medicinal product Acoziborole Winthrop, intended for the treatment human African trypanosomiasis (HAT) due to *Trypanosoma brucei gambiense* (g-HAT). Acoziborole Winthrop was reviewed under EMA's accelerated assessment programme.

The applicant for this medicinal product is Sanofi Winthrop Industrie.

Acoziborole Winthrop will be available as 320 mg tablets. The active substance of Acoziborole Winthrop is acoziborole, an antiprotozoal (ATC code: 'not yet assigned'). Available data suggest that acoziborole binds to cleavage and polyadenylation specificity factor 3 (CPSF3) in *T. brucei*, inhibiting the maturation of *T. brucei* messenger ribonucleic acid (mRNA). The boron atom in the molecular structure is thought to be essential for the trypanocidal activity, though the precise molecular interactions have not been fully characterised.

Acoziborole Winthrop has been shown to be effective at curing the disease (measured as the number of patients having no clinical signs of HAT, no detectable parasites in any fluid and a cerebrospinal fluid white blood cell count ≤ 20 cells/µl). The results showed that, after 18 months, treatment had been successful in around 95.2% (159 out of 167) of people with second-stage disease and 100% (41) of patients with first- and intermediate-stage g-HAT.

The most common side effects are pyrexia, asthenia, decreased appetite, tremor and headache.

The full indication is:

> Acoziborole Winthrop is indicated for the treatment of both first-stage (hemo-lymphatic) and second-stage (meningo-encephalitic), including severe second-stage with ≥ 100 White Blood Cell (WBC)/µL with or without trypanosomes in cerebrospinal fluid (CSF), human African trypanosomiasis (HAT) due to *Trypanosoma brucei gambiense* (g-HAT) in adolescents ≥ 12

[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] Scientific opinion in accordance with Article 58 of (EC) No Regulation 726/2004 in the context of cooperation with the World Health Organization (WHO)

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years old with body weight ≥ 40 kg, and in adults.

Acoziborole should be used in line with official recommendations (see section 4.4).

Acoziborole Winthrop should be prescribed and administered only by healthcare professionals trained in the management and treatment of HAT.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website.

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