



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Fexinidazole Winthrop (*fexinidazole*)

An overview of Fexinidazole Winthrop and why it received a positive opinion

### What is Fexinidazole Winthrop and what is it used for?

Fexinidazole Winthrop is a medicine for treating sleeping sickness (African trypanosomiasis) caused by a parasite known as *Trypanosoma brucei gambiense*. It is intended for use [outside the EU](#).

Sleeping sickness occurs in some parts of Africa and is spread through the bite of infected tsetse flies. In the first few days after being bitten, patients may have symptoms such as fever, headache and rash. Later, they may experience a more severe form of the disease, which affects the nervous system, causing symptoms such as sleep disturbances and changes in behaviour. Without treatment, the disease is usually fatal.

Fexinidazole Winthrop is for patients who are 6 years or older and weigh more than 20 kilograms. It contains the active substance fexinidazole.

### How is Fexinidazole Winthrop used?

Fexinidazole Winthrop is available as tablets (600 mg) to be taken once a day with food for 10 days.

Patients weighing 35 kilograms or more should take 3 tablets a day for the first 4 days and 2 tablets a day for the next 6 days. For patients weighing between 20 and 35 kg the daily dose is 2 tablets for the first 4 days and 1 tablet for the next 6 days.

Treatment should be supervised by trained healthcare staff who should ensure that the patients takes their tablets as required and with food. For more information about using Fexinidazole Winthrop, see the package leaflet or contact your doctor or pharmacist.

### How does Fexinidazole Winthrop work?

The active substance in Fexinidazole Winthrop, fexinidazole, is believed to work by activating certain enzymes within the parasites, which then produce substances known as reactive amines. These substances are toxic to the parasites and can help clear them from the body.



## **What benefits of Fexinidazole Winthrop have been shown in studies?**

A main study of 394 patients with sleeping sickness affecting the nervous system showed that Fexinidazole Winthrop was effective at clearing the parasites from the body in 91% of patients 18 months after treatment.

In this study, Fexinidazole Winthrop was less effective in patients with severe disease than the standard treatment – nifurtimox eflornithine plus combination therapy (NECT) – which had a success rate of 98%. However, Fexinidazole Winthrop (which is taken by mouth) is easier to use than NECT, which requires infusions (drips) into a vein in addition to treatment by mouth.

In another study in 230 patients with less severe sleeping sickness, the success rate with Fexinidazole Winthrop was 99% 12 months after the end of treatment.

## **What are the risks associated with Fexinidazole Winthrop?**

The most common side effects with Fexinidazole Winthrop (which may affect more than 1 in 10 people) include vomiting, nausea (feeling sick), weakness, loss of appetite, headache, difficulty sleeping, tremors and dizziness. For the full list of side effects of Fexinidazole Winthrop, see the package leaflet.

Fexinidazole Winthrop must not be used in patients who are hypersensitive (allergic) to fexinidazole or any medicines of the same class or to any of the ingredients in the medicine. It must also not be used in certain patients with signs of liver problems or those at risk of heart rhythm problems. For the full list of restrictions, see the package leaflet.

## **Why did Fexinidazole Winthrop receive a positive opinion?**

Fexinidazole Winthrop is effective at eliminating the parasites that cause sleeping sickness. Although it is less effective against severe forms of the disease than NECT, the standard treatment, Fexinidazole Winthrop could be made available more easily to patients in parts of Africa where the illness occurs.

As for its safety, side effects such as vomiting are generally manageable. Certain patients at risk of side effects, such as patients with pre-existing heart rhythm problems, will not be given this medicine.

The European Medicines Agency therefore concluded that Fexinidazole Winthrop's benefits are greater than its risks in patients with sleeping sickness.

## **What measures are being taken to ensure the safe and effective use of Fexinidazole Winthrop?**

Recommendations and precautions to be followed by trained healthcare staff and patients for the safe and effective use of Fexinidazole Winthrop have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Fexinidazole Winthrop are continuously monitored. Side effects reported with Fexinidazole Winthrop are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Fexinidazole Winthrop**

The European Medicines Agency gave a positive opinion for Fexinidazole Winthrop on 15 November 2018.

The Agency assessed Fexinidazole Winthrop as part of the its cooperation with the World Health Organization, whereby the Agency evaluates medicines that are not intended for use in the EU but are needed to prevent or treat diseases of major public health importance around the world.

Further information on Fexinidazole Winthrop can be found on the Agency's website: [ema.europa.eu/medicines/human/EPAR/Fexinidazole-Winthrop](https://ema.europa.eu/medicines/human/EPAR/Fexinidazole-Winthrop)

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