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# Withdrawal of application for the marketing authorisation of Ifinwil (eflornithine)

Norgine B.V. withdrew its application for a marketing authorisation of Ifinwil for the treatment of adults and children from one year of age with high-risk neuroblastoma (cancer of nerve cells in different parts of the body).

The company withdrew the application on 18 July 2025.

## What is Ifinwil and what was it intended to be used for?

Ifinwil was developed as a medicine to treat adults and children from one year of age with neuroblastoma, a cancer of nerve cells in different parts of the body. It was intended for use in patients whose disease was at high risk of coming back after initial treatment.

Ifinwil contains the active substance eflornithine and was to be available as tablets to be taken by mouth.

Ifinwil was developed as a 'hybrid medicine'. This means that Ifinwil contains the same active substance as an authorised 'reference medicine' (in this case, Vaniqa), but there are differences between the two. While Vaniqa is a cream used for the treatment of facial hirsutism (excessive growth of coarse hair on the face) in women, Ifinwil was to be available as tablets intended for the treatment of high-risk neuroblastoma.

Ifinwil was designated an 'orphan medicine' (a medicine used in rare diseases) on 20 May 2021 for the treatment of neuroblastoma. Further information on the orphan designation can be found on the Agency's website.

## How does Ifinwil work?

The active substance in Ifinwil, eflornithine, works by blocking the action of an enzyme called ornithine decarboxylase, which is involved in the production of substances called polyamines that are required for cells to grow. By blocking the enzyme, eflornithine was expected to slow down the progress of neuroblastoma.

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## What did the company present to support its application?

The company presented the results of one main study involving 140 children and young adults (between 1 and 21 years of age) with high-risk neuroblastoma who were in remission (a period without disease symptoms) following previous treatment with standard therapy. The main measure of effectiveness was how long patients lived without a complication or signs of disease occurring or coming back, measured after two years of treatment with Ifinwil. In this study, Ifinwil was not compared with any other medicine.

## How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. The company had not responded to the questions at the time of the withdrawal.

## What did the Agency recommend at that time?

Based on the review of the data, at the time of the withdrawal the Agency had some concerns, and its provisional opinion was that Ifinwil could not have been authorised for the treatment of high-risk neuroblastoma.

In particular, the Agency considered that the effectiveness of the medicine could not be demonstrated based on the data provided, due to limitations in the study design and uncertainties related to the conduct of the study and its results. The Agency also had concerns over the quality and manufacturing of the medicine.

Therefore, at the time of the withdrawal, the Agency's opinion was that the company had not provided enough data to support the authorisation of Ifinwil.

## What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that it required additional time to comprehensively address all the questions raised by the Agency.

## Does this withdrawal affect patients in clinical trials or compassionate use programmes?

The company informed the Agency that there are no immediate consequences for patients in clinical trials or in compassionate use programmes using Ifinwil.

If you are in a clinical trial or compassionate use programme and need more information about your treatment, speak with your doctor.