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Withdrawal of application for the marketing authorisation of Nurzigma (pridopidine)

Prilenia Therapeutics B.V. withdrew its application for the marketing authorisation of Nurzigma, a medicine intended for the treatment of adults with Huntington's disease.

The company withdrew the application on 7 November 2025.

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

Nurzigma was developed as a medicine for the treatment of adults with Huntington's disease. Huntington's disease is an inherited condition that worsens over time and causes brain cells to die. This leads to problems with movement, cognition (perception, awareness, thinking and judgement) and mental health.

During the assessment, the company proposed to restrict the indication to adults with early Huntington's disease who are not treated with antidopaminergic medicines. These medicines are commonly used in patients with Huntington's disease to treat chorea (jerky and involuntary movements) and behavioural symptoms (such as aggression).

Nurzigma contains the active substance pridopidine and was to be available as hard capsules.

Nurzigma was designated an 'orphan medicine' (a medicine used in rare diseases) on 20 June 2005 for the treatment of Huntington's disease. Further information on the orphan designation can be found on the Agency's website: ema.europa.eu/medicines/human/orphan-designations/eu-3-05-288.

How does Nurzigma work?

The active substance in Nurzigma, pridopidine, activates a protein called sigma-1 receptor (S1R). S1R is found inside the cells and is involved in cellular processes that contribute to the health and survival of nerve cells. By activating S1R, pridopidine was expected to improve cellular processes that are involved in nerve cell damage and Huntington's disease.

What did the company present to support its application?

The company presented results from a main study involving 499 adults aged 25 years and older with early Huntington's disease. Patients in the study were given either Nurzigma or placebo (a dummy

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treatment). The main measure of effectiveness was the change in the total functional capacity (TFC) score after 65 weeks of treatment. The TFC score measures how well a person with a disease that affects the nervous system can perform daily tasks and activities. The company also presented results from analyses in a subgroup of 208 patients from the main study, namely adults with early Huntington's disease who were not treated with antidopaminergic medicines. In addition, the company presented results from 3 supportive studies in adults with Huntington's disease.

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

The initial evaluation finished in July 2025 when the European Medicines Agency recommended refusing marketing authorisation. The company then requested a re-examination of the Agency's recommendation, but it withdrew the application before this re-examination had finished.

What were the main reasons for refusing the marketing authorisation?

At the time of the initial evaluation, the Agency considered that the main study and the supportive studies failed to provide evidence that Nurzigma is effective in patients with early Huntington's disease. The Agency noted that the validity and relevance of the results of the analyses in the subgroup of patients (adults with early Huntington's disease who were not treated with antidopaminergic medicines) from the main study have not been demonstrated.

Therefore, the Agency's opinion was that the effectiveness of Nurzigma had not been demonstrated. Although the company applied for a conditional marketing authorisation, the medicine did not meet the criteria for granting this type of authorisation. As a result, the Agency recommended refusing the conditional marketing authorisation.

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 the withdrawal was based on the need to collect additional clinical data to fully address the questions raised by the Agency's human medicines committee (CHMP).

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

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

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