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Withdrawal of application for the marketing authorisation of Omforro (midazolam)

Regulatory Pharma Net S.r.l. withdrew its application for a marketing authorisation of Omforro for the conscious sedation (to calm or make people sleepy) before or during diagnostic or surgical procedures where the patient remains awake (conscious sedation), or as premedication before anaesthesia.

The company withdrew the application on 12 September 2025.

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

Omforro was developed as a medicine for conscious sedation (to calm or make people sleepy) before or during diagnostic or surgical procedures where the patient remains awake (conscious sedation). It was also intended for use as premedication before anaesthesia. It was to be used in adults and children from 2 years of age.

Omforro contains the active substance midazolam and was to be available as a nasal spray.

Omforro was developed as a 'hybrid medicine'. This means that Omforro contains the same active substance as an authorised 'reference medicine' but there are differences between the two. The reference medicine, Ipnovel, is available as a solution for injection while Omforro was to be available as a nasal spray.

How does Omforro work?

The active substance in Omforro, midazolam, belongs to a class of sedative medicines called benzodiazepines. It attaches to receptors (targets) for the neurotransmitter gamma-amino butyric acid (GABA) in the brain and activates them. Neurotransmitters such as GABA are chemicals that allow nerve cells to communicate with each other. In the brain, GABA is involved in reducing the electrical activity. By activating the GABA receptors, midazolam slows down brain activity, which makes the person feel relaxed and sleepy. The extent of the effects of Omforro on brain activity depends on the dose given and the other medicines used during the procedure.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What did the company present to support its application?

The company provided the results of studies looking at how Omforro behaves in the body, and how it is absorbed, modified and removed from the body.

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 Omforro could not have been authorised for conscious sedation or as premedication before anaesthesia.

EMA had concerns that the data provided were not sufficient to support the intended use and the dose proposed for use in children. There were also concerns about the quality of Omforro. An evaluation of the risk of the medicine containing nitrosamines, an impurity, was missing. Furthermore, some information about the control and validation of the manufacturing process, as well as information about the nasal spray device used in the studies, was missing.

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

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 they were not in a position to provide responses to the CHMP within the timeframe established in the procedure.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Omforro.

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