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EMA recommends authorisation of Nasolam (midazolam, nasal spray) in the EU

On 27 January 2022, the European Medicines Agency completed a review of Nasolam following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Nasolam outweigh its risks and the marketing authorisation should be granted in the Netherlands and in the Member States of the EU and other countries where the company has applied for a marketing authorisation: Denmark, Germany, Finland, Ireland, Norway Sweden, and the United Kingdom (Northern Ireland).

What is Nasolam?

Nasolam is a medicine used to stop prolonged acute (sudden) convulsive seizures. It is also given to patients undergoing general anaesthesia or used to sedate patients undergoing a diagnostic or surgical procedure where they remain awake.

Nasolam is available as a nasal spray and contains the active substance midazolam, which belongs to a class of medicines called benzodiazepines.

Nasolam was developed as a hybrid medicine. This means that it is similar to a reference medicine already authorised in the EU containing the same active substance. However, the reference medicine, Dormicum, is a solution given intravenously (as an injection into the vein) and is not used to treat prolonged acute convulsive seizures.

Why was Nasolam reviewed?

Tiofarma B.V. submitted Nasolam to the Netherlands for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance the Netherlands) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance Denmark, Germany, Finland, Ireland and Sweden, as well as Norway and the United Kingdom [Northern Ireland]), where the company has applied for a marketing authorisation.

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

However, the Member States were not able to reach an agreement regarding the use of the medicine to stop prolonged acute convulsive seizures, and the Dutch medicines regulatory agency referred the matter to EMA for arbitration on 24 September 2021.

The main grounds for the referral were concerns raised by the Swedish medicines agency about the safety and effectiveness of the medicine when used to treat prolonged acute convulsive seizures in the non-hospital setting. For this use, the company submitted data for an intrabuccal midazolam solution (intrabuccal means the medicine is given in the side of the mouth, between the cheek and the gum), authorised as Buccolam in the EU. The Swedish agency had concerns that the data could not show that midazolam given as a nasal spray is absorbed similarly to the intrabuccal form of midazolam and is similar in terms of safety and effectiveness.

What is the outcome of the review?

The Agency concluded that currently available data, including data on the level of the active substance in the blood over time and literature data on the use of midazolam to treat seizures, supported the use of intranasal midazolam in the treatment of seizures. The Agency concluded that the benefits of Nasolam in stopping prolonged acute convulsive seizures outweigh its risks and that the marketing authorisation for Nasolam should be granted in all concerned Member States. The Agency also recommended amending parts of the product information relating to dosing for older patients and further instructions for carers on the use of a second dose when treating seizures.

More about the procedure

The review of Nasolam was initiated on 24 September 2021 at the request of the Netherlands, under Article 29(4) of Directive 2001/83/EC.

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use.

The European Commission issued an EU-wide legally binding decision on the marketing authorisation of Nasolam on 1 April 2022.