

Summary Public Assessment Report

Senozam (midazolam)

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Senozam
midazolam

Solution for infusion, 1 mg/ml, 5 mg/ml

This is a summary of the public assessment report (PAR) for Senozam. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Senozam and what is it used for?

The product is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Senozam contains midazolam which belongs to a group of medicines called benzodiazepines (sedatives).

Midazolam works quickly to make you feel sleepy or to put you to sleep. It also makes you calm and relaxes your muscles.

Senozam, solution for infusion is used for:

- “*Conscious sedation*” (an awake but very relaxed state of calm or drowsiness during a medical test or procedure) in adults and children aged 2 years and older.
- Sedation of adults and children aged 28 days and older, in intensive care units.
- Anaesthesia in adults, in combination with other medicines.
- Premedication (medicine used to cause relaxation, calm and drowsiness before an anaesthetic) in adults.

How does Senozam work?

Senozam contains midazolam which belongs to a group of medicines called benzodiazepines (sedatives).

Midazolam works quickly to make you feel sleepy or to put you to sleep. It also makes you calm and relaxes your muscles.

How is Senozam used?

The pharmaceutical form is solution for infusion for use in infusions.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Senozam have been shown in studies?

As *midazolam* is a well-known substance, and its use in the treatment of

- **Conscious sedation** before and during diagnostic or therapeutic procedures with or without local anaesthesia

- **Anaesthesia**

- Premedication before induction of anaesthesia
- As a sedative component in combined anaesthesia.

- **Sedation in intensive care units**

In children

- **Conscious sedation** before and during diagnostic or therapeutic procedures with or without local anaesthesia for children above 2 years

- **Sedation in intensive care units in combination with the analgesic morphine or fentanyl for infants above 28 days**

is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of *midazolam* in the treatment of the above-mentioned indication.

What are the possible side effects from Senozam?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Senozam approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Senozam?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Senozam

The full PAR for Senozam can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Senozam, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-01.