

Package leaflet: Information for the user

Senozam 1 mg/ml, solution for infusion

Senozam 5 mg/ml, solution for infusion

midazolam

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Senozam is and what it is used for
2. What you need to know before you are given Senozam
3. How Senozam is given
4. Possible side effects
5. How to store Senozam
6. Contents of the pack and other information

1. What Senozam is and what it is used for

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.

2. What you need to know before you are given Senozam

You should not be given Senozam:

- if you are allergic to midazolam or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other benzodiazepines, such as diazepam or nitrazepam.
- if you have severe breathing problems and you are going to have Senozam for “*conscious sedation*”.

You must not be given Senozam if any of the above applies to you. If you are not sure, talk to your doctor or nurse before you are given this medicine.

Warnings and precautions

Talk to your doctor or nurse before you are given Senozam:

- if you are over 60 years of age.
- if you are debilitated or have a long term illness, such as breathing problems or kidney, liver or heart problems.
- if you have 'myasthenia gravis' (a neuromuscular disease causing muscle weakness).

- if you have sleep apnoea.
- if you have or have ever had alcohol or drug problems.

This medicine should only be used in the presence of age and body size adapted resuscitation facilities because the intravenous administration might influence the myocardial contractility (the ability of the heart muscle to contract) and cause interruptions in breathing (apnea). In rare cases, serious cardio-respiratory adverse reactions have occurred. This included respiratory depression, apnea, respiratory arrest and / or cardiac arrest. Such life-threatening incidents can be prevented by slow injection and to keep the dose as low as possible.

When this drug is used for premedication you will be closely observed. Your response determines whether you have received the correct dose as sensitivity varies between patients.

Paradoxical reactions (unexpected) and anterograde amnesias (loss of short term memory) have occurred after using this medicine (see section 4 “Possible side effects”).

Children

Special precautions should be taken when this medicine is given to infants or children. It is particularly important to tell your doctor if your child has a cardiovascular disease or breathing problem. Your child will be properly monitored and the dose will be adjusted.

Children must be carefully monitored. For infants less than 6 months of age this will include monitoring of breathing and oxygen levels.

The use of this medicine in children under 2 years of age is not recommended, except for sedation in intensive care units if the child is 28 days of age or older.

Long-term treatment

If you are treated with this medicine for a long time, you may develop tolerance (this medicine becomes less effective) or develop dependence on this medicine.

After long-term treatment (for example in intensive care) the following withdrawal symptoms can occur: headache, diarrhea, muscle pain, anxiety, tension, restlessness, confusion, irritation, trouble sleeping, mood swings, hallucinations and convulsions. In severe cases feelings of unreality, numbness and tingling of the hands and feet, hypersensitivity to light, noise and physical contact may occur. Your doctor will gradually reduce the dose to avoid getting such side effects.

After discharge

After having Senozam you can feel sleepy, dizzy or forgetful and your muscular function and attention may be impaired. You will therefore be discharged from the hospital or consulting room only when recommended by the treating physician and only if accompanied by an attendant. It is recommended that you are accompanied when returning home after discharge. Do not drive or use machines until your doctor says you can.

Other medicines and Senozam

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because midazolam can affect the way some other medicines work. Also some other medicines can affect the way midazolam works. In particular, tell your doctor or nurse if you are taking any of the following medicines:

- Tranquilliser medicines (for anxiety or to help you sleep)
- Hypnotic medicines (to help you sleep)
- Sedatives (to make you feel calm or sleepy)
- Narcotic analgesics (very strong pain killers)
- Opioids (strong pain killers, medicines for substitution therapy and some cough medicines)
- Anti-histamines (for allergic reactions)
- Medicines to treat fungal infections (such as ketoconazole, voriconazole, fluconazole, itraconazole, posaconazole)

- Antibiotics called 'macrolides' (such as erythromycin or clarithromycin)
- Diltiazem (used to treat high blood pressure)
- Medicines for HIV called 'protease inhibitors' (such as saquinavir, lopinavir)
- Atorvastatin (for high cholesterol)
- Rifampicin (used to treat tuberculosis)
- Ticagrelor (used to prevent stroke, heart attack and blood clots)
- St John's Wort (a herbal medicine for depression)
- Antipsychotics (to treat psychosis)
- Barbiturates (to make you feel calm or sleepy or to treat epilepsy)
- Sedative antidepressants (to help you sleep)
- Centrally acting antihypertensive drugs (to treat high blood pressure)

Combined use of Senozam and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be lifethreatening. Because of this, combined use should only be considered when other treatment options are not possible. However if your doctor does prescribe Senozam together with opioids the dose and duration of combined treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Surgeries

If you are going to have an anesthetic (inhaled, one that you breathe in, or a non inhaled) for surgery or dental treatment, it is important to tell your doctor or dentist that you have been given midazolam.

Senozam with alcohol

Do not drink alcohol if you have been given Senozam. This is because it may make you feel very sleepy and cause problems with your breathing.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide if this medicine should be given to you or not.

- The use of this medicine during the final stage of pregnancy, during delivery or during caesarean section can cause irregular heartbeat, hypotonia (low muscle tone), feeding problems, low body temperature and difficulty breathing in your baby. For you, the use of this medicine during delivery can cause breathing problems.
- Long-term treatment with this medicine during the last phase of your pregnancy can cause physical dependence in your baby and withdrawal symptoms may occur after birth.
- Senozam passes into breast milk in small quantities. You should not breast-feed for 24 hours after receiving Senozam.

Driving and using machines

After having Senozam, do not drive, cycle or use tools and machines until your doctor says you can. This is because Senozam may make you feel sleepy, dizzy or forgetful. It may also affect your concentration and co-ordination. This may affect you being able to drive, cycle or use tools and machines. After your treatment, you must be taken home by an adult who can look after you.

Senozam contains sodium

Senozam 1 mg/ml contains 357mg sodium (main component of cooking/table salt) per 100 ml. This is equivalent to 17,85% of the recommended maximum daily dietary intake of sodium for an adult. Senozam 5 mg/ml contains 220 mg sodium (main component of cooking/table salt) per 100 ml. This is equivalent to 10,96% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Senozam is given

Senozam will be given to you by a doctor or nurse. It will be given to you in a place that has the equipment needed to monitor you and to treat any side effects. This might be a hospital, clinic or doctor's surgery. In particular, your breathing, heart and circulation will be monitored.

Dose and method of administration

The dose of midazolam varies from one patient to another. The doctor will work out how much to give you. It depends on your age, weight and general health. It also depends on what you need the medicine for, how you respond to treatment, and whether you are going to be given other medicines at the same time.

If you need strong painkillers, you will be given them first and the dose of Senozam will be adjusted for you.

Senozam will be given to you by slow injection into a vein (intravenous injection), through a drip into one of your veins (intravenous infusion), or by injection into a muscle (intramuscular injection). After your treatment, you must be taken home by an adult who can look after you.

Use in children

Senozam is not recommended in neonates under the age of 28 days, as available data are limited.

- In children under 2 years of age but aged 28 days and over Senozam is only recommended for sedation in intensive care units. The dose will be given gradually into a vein.
- For conscious sedation children are usually given midazolam into a vein.

If you are given more Senozam than you should

Your medicine will be given to you by a doctor or nurse. This means it is unlikely that you will be given too much. However, if you are given too much by mistake, you may notice the following:

- Feeling sleepy and losing your co-ordination and reflexes.
- Problems with speaking and unusual eye movements.
- Low blood pressure. This may make you feel dizzy or light-headed.
- Slowing or stopping of your breathing or heart beat and being unconscious (coma).

In case of overdose your doctor may carefully monitor your vital signs and treatment of any effects on heart and breathing may be required as well as the use of medicines to counteract the effects of benzodiazepine.

If use of Senozam is stopped

If you are given Senozam for a long time, such as in intensive care, you may get withdrawal symptoms when you stop being given the medicine. These include: headache, diarrhea, muscle pain, anxious, tense, restless, confused, bad tempered (irritable), problems with sleeping, mood changes, hallucinations, convulsions. The risk of such withdrawal symptoms is greater if treatment is discontinued abruptly and therefore your doctor will lower your dose gradually.

If you have any further enquiries about the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported but their frequency is not known and cannot be estimated from the available data.

Stop having Senozam and see a doctor straight away if you notice any of the following side effects. They can be life-threatening and you may need urgent medical treatment:

- A severe allergic reaction (anaphylactic shock) and angioedema. The signs may include a sudden rash, itching or lumpy rash (hives) and swelling of the face, lips, tongue or other parts of the body. You

may also have shortness of breath, wheezing or trouble breathing, or a pale skin, a weak and rapid pulse, or feeling of loss of consciousness. Additionally, you may experience chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

- Cardiac arrest. The signs may include chest pain.
- Breathing problems, sometimes causing the breathing to stop.
- Muscle spasm in the airways, causing choking.

Life-threatening side effects are more likely in adults over 60 years, and in people who already have breathing or heart problems. These side effects are also more likely if the injection is given too fast or at a high dose.

Other possible side effects

Immunesystem disorders:

General allergic reactions (skin reactions, reactions of the heart and bloodsystem, wheezing).

Psychiatric disorders:

- Feeling confused, disoriented
- Feeling very happy or excited (euphoria)
- Seeing or possibly hearing things that are not really there (hallucinations)
- Losing contact with reality (psychoses)
- Feeling restless
- Feeling agitated, irritated, nervous or anxiety
- Feeling angry, aggressive or hostile
- Drug addiction, drug abuse
- Changes in libido
- Emotional and mood disturbances
- Inappropriate behaviour
- Nightmares, abnormal dreams

Nervous system disorders:

- Feeling tired or sleepy or being sedated for a long time
- Being less alert
- Headache
- Feeling dizzy
- Hyperactivity
- Difficulty co-ordinating muscles
- Fits (convulsions) in premature and new-born babies.
- Drug withdrawal convulsions
- Temporary memory loss. How long this lasts depends on how much midazolam you were given and it may also occur after the treatment. In isolated cases this has lasted for a long time.

Heart and circulation disorders:

- Low blood pressure. This may make you feel dizzy or light-headed.
- Slow heart rate
- Redness of the face and neck (flushing)
- Formation of blood clots (thrombosis)
- Swollen or inflamed vein due to a blood clot (thrombophlebitis)

Lung disorders:

- Hiccups
- Shortness of breath

Gastrointestinal disorders:

- Feeling sick (nausea)
- Vomitting
- Constipation

- Dry mouth

Skin disorders:

- Rash
- Hives (lumpy rash)
- Feeling itchy

Musculoskeletal and connective tissue disorder:

- Muscle spasms or shaking of your muscles that you cannot control (tremors)

General disorders and administration site conditions:

- Tiredness
- Redness
- Blood clots or pain at the injection site

Social Circumstances:

- Assault

Injuries, poisoning and procedural complications:

- Patients taking benzodiazepine medicines, like Senozam, have a risk of falling and breaking bones. This risk is higher in elderly people and people taking other sedative substances (such as alcohol).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse: This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Senozam

- Keep this medicine out of the sight and reach of children.
- Use this medicine immediately after opening
- Do not use this medicine after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.
- Each bag is for single use only
- This medicinal product does not require any special temperature storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Senozam contains

- The active substance is midazolam.

Senozam 1 mg/ml, solution for infusion

1 ml of solution contains 1 mg of midazolam.

1 bag with 100 ml solution for infusion contains 100 mg midazolam.

Senozam 5 mg/ml, solution for infusion

1 ml of solution contains 5 mg of midazolam.

1 bag with 100 ml solution for infusion contains 500 mg midazolam

- The other ingredients are sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections.

What Senozam looks like and contents of the pack

Senozam solution for infusion is clear and (almost) colourless and is available in transparent bags containing 100 ml solution. The bags are overwrapped in outer pouches and have two tubes. One of the tubes is to be connected to the infusion line of a pump or to an injection site. One bag is packaged in a carton.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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