

Esketamine Kalceks 5 mg/ml, 25 mg/ml solution for injection/infusion.

What is Esketamine Kalceks and what is it used for?

- This medicine belongs to a group of medicines called anesthetics. These medicines are used to put you to sleep during surgery.
- This medicine can be given alone or in combination with other anesthetics.
- This medicine can be used in emergencies as a pain reliever or to completely anesthetize someone (general anesthesia).
- This medicine can be used as an additional anesthetic alongside another medicine to numb a part of the body for surgery (regional or local anesthesia).

When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- if you are allergic to any of the ingredients in this medicine.
- if high blood pressure or increased pressure in the brain (intracranial pressure) pose severe risks for you;
- if you have a painful and pressing feeling in the chest (angina pectoris) and/or a heart disease (in this case, this medicine should not be used as the sole anesthetic);
- if you have a condition called eclampsia or pre-eclampsia (problem during pregnancy that causes high blood pressure); together with xanthine derivatives or ergometrine (used to start contractions).

Do any of the above apply to you? Then you should not receive this medicine.

When should you be extra careful with this medication?

Contact your doctor or nurse before taking this medication. They can decide if this medication is suitable for you:

- if you have less blood or fluid in your body, dehydration;
- if you have a heart disease (the heart pumps blood less effectively (heart failure), coronary heart disease) and high blood pressure that has not yet been treated;
- if you have chest pain or have had a heart attack in the last 6 months;
- if you have an irregular heartbeat;
- if you have increased pressure in the brain and a disease or injury to your brain, nerves, or spinal cord (central nervous system). Some patients who have had ketamine (a drug similar to Esketamine Kalceks) as a sedative have had increased pressure in the brain;
- if you have pneumonia or an inflammation of the upper respiratory tract;
- if you have increased eye pressure (such as glaucoma) or if you have a wound in your eye where your eyeball is broken (penetrating injury). Or if you need an eye exam or eye surgery where the eye pressure should not be higher;
- if you have a disease called "acute intermittent porphyria" (a rare metabolic problem);
- if you drink alcohol;
- if you have severe mental problems or have had them in the past;
- if your thyroid is working too fast (your hyperthyroidism is not adequately treated);
- if you have liver disease;
- if you have a history of drug abuse or have been addicted.

This medication should be used with caution if the uterine muscles need to be relaxed during delivery (there is a risk of uterine rupture or prolapsed umbilical cord).

Treatment in the hospital

After treatment in the hospital, you should be accompanied home and should not drink alcohol for the first 24 hours.

Are you taking other medications?

Are you taking other medications along with Esketamine Kalceks, have you done so recently, or are you planning to do so soon? Tell your doctor or nurse.

Tell your doctor or nurse if you have recently taken any of the following medications:

- sympathomimetics (such as adrenaline or noradrenaline), thyroid hormone, vasopressin (can cause high blood pressure, faster heart rate, or irregular heartbeat);
- xanthine derivatives (such as aminophylline, theophylline), which can cause muscle cramps or epileptic seizures. Therefore, xanthine derivatives should not be used with Esketamine Kalceks;
- sleeping pills, benzodiazepines (such as diazepam), or antipsychotics (used for mental health problems). This may cause Esketamine Kalceks to work longer than normal;
- barbiturates and opioids (such as morphine) given together with Esketamine Kalceks can prolong the recovery from anesthesia;
- the anesthetic effect of some gas anesthetics (such as halothane, isoflurane, desflurane, sevoflurane) is increased by the use of Esketamine Kalceks. Therefore, a lower dose of the gas anesthetic may be required; muscle relaxants (such as pancuronium or suxamethonium), as they may prolong the effect of Esketamine Kalceks;
- do not use Esketamine Kalceks together with ergometrine (used to start contractions);
- medicines that inhibit the function of the CYP3A4 enzyme. If these medications are used together with Esketamine Kalceks, a lower dose of Esketamine Kalceks may be required;
- medicines that strengthen the function of the CYP3A

What should you pay attention to regarding eating, drinking, and alcohol?

As with all medications used to fully anesthetize someone for surgery (general anesthesia), you must not eat or drink anything for 4 to 6 hours before receiving this medication. You should not consume alcohol within 24 hours after taking this anesthesia medication.

Pregnancy and breastfeeding: Are you pregnant, think you might be pregnant, want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medication.

Pregnancy: This medication is not used during pregnancy unless your doctor finds that the benefit of treatment is greater for you than the possible risk to the baby. This medication can cause breathing problems (reduced breathing) in your baby if it is used during delivery.

Breastfeeding: The medication can pass into breast milk. It is likely that the baby will not be affected if it is used in the recommended doses.

Driving and operating machinery: There is a chance that you will react slower due to this medication. Keep this in mind if you need to be extra careful, such as when driving a car. Therefore, you should not drive a car or operate machinery for at least 24 hours after receiving this medication. Contact your doctor or nurse if you are not sure if it is safe for you to drive a car or operate machinery.

Esketamine Kalceks contains sodium

- Esketamine Kalceks 5 mg/ml contains 3.2 mg of sodium per milliliter of solution (sodium is an important component of table salt). This corresponds to 0.16% of the recommended maximum daily intake of sodium in the diet for an adult.
- Esketamine Kalceks 25 mg/ml contains 1.2 mg of sodium per milliliter of solution (sodium is an important component of table salt). This corresponds to 0.06% of the recommended maximum daily intake of sodium in the diet for an adult.

How is this medicine administered?

You will only receive this medicine in a hospital or emergency department by or under the supervision of an anesthesiologist (anesthesia specialist).

You will receive this medicine as a slow injection into your vein or muscle. If necessary, a new injection may be given or the preparation may be administered as an infusion.

In patients with liver disease (cirrhosis) or other diseases where the liver does not function well, the dose may need to be reduced.

If you have any other questions about using this medicine, please contact your doctor, nurse, or anesthesiologist.

Possible side effects

Like all medicines, this medicine can have side effects. Not everyone experiences them. Side effects usually depend on the dose and rate of injection and usually disappear without treatment.

Common (affecting less than 1 in 10 users): Reactions during recovery from anesthesia, such as vivid dreams, nightmares, dizziness, and motor restlessness (you may experience muscle cramps, shaking, or inability to sit still). Blurred vision. Temporary increase in heart rate, increase in blood pressure. Side effects on breathing during anesthesia. Nausea and vomiting, your body produces more saliva.

Sometimes (affecting less than 1 in 100 users) • Increased body movements (such as muscle spasms), which may resemble cramps, increased eye movements. • Double vision, increased pressure in the eye. • Skin rash. • Pain and/or redness at the injection site.

Rarely (affecting less than 1 in 1,000 users): • Severe allergic reactions. • Irregular heartbeat, slow heartbeat. • Low blood pressure.

How to store this medicine?

Keep out of sight and reach of children.

There are no special storage conditions for this medicine.

Do not use this medicine after the expiry date. This can be found on the label of the ampoules and on the cardboard box after EXP. It states a month and a year. The last day of that month is the expiry date.