

Package leaflet: Information for the user

Ketamin Abcur 10 mg/ml solution for injection **Ketamin Abcur 50 mg/ml solution for injection**

ketamine

Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ketamin Abcur is and what it is used for
2. What you need to know before you are given Ketamin Abcur
3. How you are given Ketamin Abcur
4. Possible side effects
5. How to store Ketamin Abcur
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1. What Ketamin Abcur is and what it is used for

- Ketamine Abcur, belongs to a group of anaesthetic agents, which are used to put you to sleep during a surgery or diagnostic procedures.
- Ketamin Abcur can be given alone as an anaesthetic drug or in combination with other anaesthetic drugs.
- Ketamin Abcur can be used before or as additional treatment for regional anaesthesia.
- Ketamin Abcur can be used for children and adults.

2. What you need to know before you are given Ketamin Abcur

You should not be given Ketamin Abcur:

- if you are allergic to ketamine or any of the other ingredients of this medicine (listed in section 6).
- if high blood pressure poses a serious risk to you,
- if you have a condition called eclampsia or preeclampsia (a pregnancy complication that causes elevated blood pressure).

If any of the above applies to you, this medicine should not be given to you.

Warnings and precautions

Talk to your doctor or nurse before you are given Ketamin Abcur if any of the following applies to you. This helps them to decide if Ketamin Abcur is suitable for you:

- if you have decreased blood volume, are dehydrated or have heart disease, especially coronary artery disease (e.g. heart failure, angina or heart attack),
- if you have high blood pressure or fast heart rate,
- if you have increased pressure in the brain or spinal cord or damage or diseases in the central nervous system,
- if you have increased pressure in the eye (e.g. glaucoma) or if you are to undergo eye examination or surgery where an increase in pressure in the eye is inappropriate,
- if you have an alcohol problem or are under the influence of alcohol,

- if you have neurotic traits or mental illness (e.g. schizophrenia and acute psychosis),
- if you have acute intermittent porphyria (impaired function of certain blood-forming enzymes which can cause increased excretion of porphyrin and discoloration of urine),
- if you have overactive thyroid gland (hyperthyroidism) or are taking thyroid medication,
- if you have an infection in your lungs or upper respiratory tract,
- if you have brain injury, head injury, eyeball injury or hydrocephalus,
- if you have liver diseases,
- if you have previously abused or been addicted to drugs.

Outpatient care

After outpatient treatment, you should not go home on your own and should abstain from alcohol for the next 24 hours.

Long-term use

Ketamin Abcur is not intended or recommended for long-term use.

Urinary tract infection, sometimes with bleeding, and liver problems have been reported, especially with longterm use (more than 3 days) or misuse of the medicine. See also section 4. Possible side effects.

Drug abuse and addiction

With daily use for several weeks, dependence and tolerance may develop, especially in individuals who have or have had a history of drug abuse or dependence. Other side effects have also been reported, see “Longterm use”.

Other medicines and Ketamin Abcur

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Ketamin Abcur may affect or be affected by other medicines:

- Concomitant use of theophylline or aminophylline and Ketamin Abcur should be avoided as this may more easily cause cramps.
- Ketamin Abcur may prolong the muscle relaxant effect of suxameton.
- Ketamin Abcur may enhance the muscle relaxant effect of atracurium and also cause respiratory depression with shortness of breath
- Medication with diazepam enhances the effect of Ketamin Abcur .
- When Ketamin Abcur and vasopressin are used simultaneously, a blood pressure-increasing effect has been observed.
- Sympathomimetic (e.g. adrenaline or norepinephrine) and vasopressin can increase blood pressure, increase heart rate or cause heart rhythm disturbances.
- Concomitant use of ergometry may lead to an increase in blood pressure.
- Barbiturates, narcotics and inhaled anaesthetics, if used concomitantly with Ketamin Abcur, may prolong the awakening.
- Concomitant use of Ketamin Abcur (especially at high doses or if administered rapidly) with anaesthetics containing halogens (so-called halogenated anaesthetics) may increase the risk of developing slow heart rate, low blood pressure or reduced cardiac output.
- Concomitant use of Ketamin Abcur and other sedatives drugs (e.g. ethanol, phenothiazines, sedative H1 blockers or muscle relaxants) may potentiate the effect on the central nervous system and / or increase the risk of respiratory depression.
- When used concurrently with other anxiolytics, sedatives and sleeping pills, it may be necessary to reduce the Ketamin Abcur dose.
- Ketamin Abcur counteract the hypnotic effect of thiopental
- Patients taking thyroid hormones are at increased risk of developing high blood pressure and rapid heart rate when receiving Ketamin Abcur .
- Concomitant use of blood pressure lowering drugs and Ketamin Abcur increases the risk of low blood pressure.
- Use of Ketamin Abcur with medicines that may reduce the activity of the liver enzyme CYP3A4 (e.g. itraconazole, fluconazole, clarithromycin, erythromycin, verapamil and, diltiazem) may require a decrease in Ketamin Abcur dose.

- Use of Ketamin Abcur with drugs that may increase the activity of the liver enzyme CYP3A4 (e.g. phenytoin, carbamazepine, St. John's wort) may require the dose of Ketamin Abcur to be increased.

Ketamin Abcur with food, drink and alcohol

It is recommended that you fasten 4-6 hours prior to surgery. You should not drink alcohol for at least 24 hours after you received Ketamin Abcur.

Pregnancy, breast-feeding and fertility

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 you are given this medicine.

Pregnancy

Use in pregnancy is not recommended, except for use during labour. If the medicine is given during labour, it may affect the baby's breathing rate.

Breast-feeding

This medicine may pass into breast milk but at recommended doses, the risk of harming the baby is unlikely. However, use during breast-feeding is not recommended.

Driving and using machines

Do not drive or use machines for at least 24 hours after receiving Ketamin Abcur. Ketamine Abcur reduces the ability to react, which may be important in situations where increased attention is required, such as when driving.

Ketamin Abcur 10 mg/ml contains sodium

Ketamin Abcur 10 mg/ml contains less than 1 mmol sodium (23 mg) ml, i.e. essentially 'sodium-free'.

3. How you are given Ketamin Abcur

Ketamin Abcur not intended or recommended for long-term use.

Ketamin Abcur is only given by or under supervision of an anaesthetist (a specialist in anaesthesia).

The medicine is given as slow injection into a blood vessel (intravenously) or in a muscle (intramuscularly). If necessary, the injection can be repeated or the preparation can be given as a drip (infusion).

If you have further questions about this medicine, ask your doctor or nurse.

If you have received too much Ketamin Abcur

As this medicine will be given to you by healthcare professionals, it is unlikely that you will receive too much medicine.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects are mostly related to dose and injection rate and usually disappear without treatment.

Common side effects (may affect up to 1 in 10 people):

- Hallucinations, abnormal dreams, nightmares, confusion, agitation, abnormal behaviour
- Increased body movements (e.g. muscle twitching) that may be resemble fits and increased eye movements,
- Double vision,
- Elevated blood pressure, fast heart rate,

- Faster breathing,
- Nausea, vomiting and increased salivation,
- Redness of the skin, measles-like rash.

Uncommon side effects (may affect up to 1 in 100 people)

- Anorexia,
- Anxiety, worry,
- Increased pressure in the eye,
- Irregular or slow heart rate,
- Low blood pressure,
- Effects on breathing, spasm of the muscles of the larynx,
- Skin rash,
- Increased muscle tension,
- Pain and/or rash at the injection site.

Rare side effects (may affect up to 1 in 1000 people):

- Severe allergic reactions,
- Delirium, flashback, depression, insomnia, disorientation,
- Lung disease, shortness of breath.

Side effect where the occurrence is not known (frequency cannot be estimated from the available data)

- Abnormal liver function tests,
- Liver damage in prolonged use (> 3 days) or drug abuse.

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 Ketamin Abcur

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

It is recommended that the product is used as soon as possible after it is mixed with solvent, although it may be stored if the instructions at the end of the leaflet are strictly followed.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Ketamin Abcur contains

- The active substance is ketamine
10 mg/ml: Each ml solution for injection contains ketamine hydrochloride equivalent to 10 mg ketamine
50 mg/ml: Each ml solution for injection contains ketamine hydrochloride equivalent to 50 mg ketamine
- The other ingredients are :
10 mg/ml: water for injections, sodium hydrochloride
50 mg/ml: water for injections

What Ketamin looks like and contents of the pack

Ketamin Abcur is a clear colourless solution for injection (injection).

Ketamine Abcur 10 mg/ml:	5 ml glass ampoules in boxes of 5, 10, 20, 50 or 100 ampoules
Ketamine Abcur 50 mg/ml	5 ml glass ampoules in boxes of 5, 10, 20, 50 or 100 ampoules 10 ml glass ampoules in boxes of 5, 10, 20, 50 or 100 ampoules

Marketing Authorisation Holder

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The following information is intended for healthcare professionals only.

Ketamin Abcur should only be administered by or under supervision of medically qualified anaesthetists. Equipment to ensure the vital functions should be available.

Incompatibilities

Ketamine is chemically incompatible with barbiturates and diazepam because of formation of precipitate. Therefore, these should not be mixed in the same syringe or infusion fluid.

Shelf life

Before opening: 3 years

After opening: Chemical and physical in-use stability has been demonstrated for 48 hours at 25 °C. From microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Special precautions for handling

Ketamin Abcur can be diluted with 50 mg/ml (5%) glucose solution and 9 mg/ml (0,9 %) sodium chloride.