



Ketamine Therapy Informed Consent

Since the early 1960s, the Food and Drug Administration (FDA) has required drugs used in the United States to be both safe and effective. The label information on the container, in the package insert, in the Physician's Desk Reference (PDR) and in any advertising can indicate a drug's use only in certain "approved" doses and routes of administration for a particular condition. The use of a drug for a disease not listed on the label, or in a dose, or by a route not listed on the label is considered to be an "off-label" use of the drug. Physicians, based on their knowledge and on available current information, may use a drug for a use not indicated in the "approved" labeling if it seems reasonable or appropriate. **Ketamine has not been approved by the FDA to treat pain or any mental health disorder.**

1. PROCEDURE

A) INFUSION THERAPY

An intravenous line (IV) will be started in an arm so you can receive ketamine. Your blood pressure, heart rate, and oxygen saturation will all be monitored throughout the infusion under the supervision of a physician.

B) INJECTION THERAPY

Ketamine may be injected under the skin for treatment in the office. This will only be done after dosing and side effects are first established with infusion therapy.

C) HOME USE

When infusion and office use is not practical, or as-needed dosing for breakthrough pain is the intended use, ketamine may be provided as a lozenge or nasal spray.

Special care must be taken to store the medication in a safe location, out of the reach of children, and never use more than prescribed. This medication cannot be combined with alcohol or other mind-altering substances. It must



only be used at home when the environment is safe and other tasks are not required of you.

Ketamine used daily or frequently over a long period of time has not been studied, and long-term side effects are not known.

2. RISKS/SIDE EFFECTS

Side effects normally depend on the dose and how quickly it is given. The dose being used is lower than anesthetic doses.

Common side effects, greater than 1% and less than 10%:

- Hallucinations
- Out-of-body experience
- Nausea and vomiting
- Increased saliva production
- Dizziness
- Blurred vision
- Increased heart rate and blood pressure
- Poor balance, difficulty walking and impaired motor skills

These symptoms dissipate when ketamine is stopped. You should not drive the day of treatment and can resume driving the following day.

Uncommon side effects, greater than 0.1% and less than 1%:

- Rash
- Double vision
- Increased pressure in the eye
- Tremor

Rare side effects, greater than 0.01% and less than 0.1%:

- Allergic reaction
- Irregular or slow heart rate



- Low blood pressure
- Bladder irritation: most commonly with frequent urination, but chronic use may result in inflammation, ulcers, and fibrosis
- Long term use or very high doses have been associated with cognitive impairment

Other Risks:

- Ketamine may not help with pain, depression, bipolar disorder, or PTSD
- Ketamine can cause various symptoms including but not limited to flashbacks, hallucinations, feelings of unhappiness, restlessness, anxiety, insomnia and disorientation.
- Risk of other medications interacting with ketamine. It is very important that you disclose all medications, both prescription and over the counter, that you are taking.
- There is a potential risk of dosing error or unknown drug interaction that may require medical intervention including intubation (putting in a breathing tube), or hospitalization.
- The risk of venipuncture may include temporary discomfort from the needle stick, bruising, or infection. Fainting may also occur.
- Long term side effects, and side effects of frequent or daily use are not known.

Benefits

Ketamine has been associated with a decrease in pain, depression, bipolar, and PTSD symptoms with results lasting for days to weeks to months. There is no way to predict how any single person will respond to ketamine therapy. These effects may not be long lasting and will most likely require further treatment. The best response is seen in conjunction with psychotherapy (talk therapy).

Risk Management

You must report any unusual symptoms or side effects at once to the medical staff.



On the day of the treatment, you may NOT engage in any of the following after the infusion:

- Driving
- Drinking alcohol or using drugs
- Conducting business
- Participating in activities which require you to rely on motor skills or memory

5. VOLUNTARY NATURE OF THE TREATMENT

You are free to choose to receive or not receive the ketamine treatment. Please tell the doctor if you do not wish to receive ketamine.

6. WITHDRAWAL OF TREATMENT

Your doctor has the right to stop treatment with ketamine at any time, with or without your consent, for any reason.

7. PATIENT CONSENT

- I know that ketamine is not an FDA approved treatment for pain depression, bipolar disorder, or PTSD.
- I know that my taking part in this treatment is my choice.
- I know that I may decide not to take part or to withdraw from the treatment at any time.
- I know that I can do this without penalty or loss of treatment to which I am entitled.
- I also know that the doctor may stop the treatment without my consent.
- I also know that ketamine infusion therapy may not help my pain, depression, bipolar, or PTSD.
- The possible alternative methods of treatment, the risks involved, benefits, and the possibility of complications have been fully explained to me.
- No guarantees or assurances have been made or given to me about the results that may be obtained.
- I have had a chance to ask the doctor questions about this treatment.
- They have answered those questions to my satisfaction.



- The nature and possible risks of a ketamine infusion have been fully explained to me.

I have read this form or have had it read to me. I understand all of it. I have had a chance to ask questions and have all of my questions regarding this treatment answered to my satisfaction. By signing this form voluntarily, I give my consent for treatment with ketamine, and affirm that I have full right and power to sign and be bound by this agreement, and that I have read, understand, and accept all of its terms.

Patient name (print): _____

Signature: _____ Date: _____

Physician Signature: _____