



AT Psychiatry, PLLC
1843 Austin Bluffs Parkway, Rm 101
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Informed Consent for Intranasal and Sublingual Ketamine Therapy

Ketamine is approved by the FDA for use in children and adults for anesthesia and as a pain reliever during medical procedures. When administered intranasally or sublingually at low-dose, ketamine may provide relief for symptoms of depression, anxiety, post-traumatic stress disorder (PTSD), and acute and chronic pain. Ketamine's use for treatment of pain, depression or other mental illnesses is off label. Off-label use of medications is considered experimental, is legal and common. In fact, about one in five prescriptions written in the US today is off label.

Why Is Ketamine Recommended?

Numerous studies show that ketamine may be helpful in the treatment of major depressive disorder, bipolar depression, anxiety, PTSD, substance use disorders, and acute and chronic pain. When administered intranasally or sublingually, ketamine may help improve symptoms rather quickly within days. Improvements may last several days up to a few weeks. A series of intranasal or sublingual administrations are recommended so that symptom relief has a longer duration. While the goal is improvement of symptoms, individual results cannot be guaranteed.

What Will Be Done?

You will be receiving ketamine intranasally or sublingually. This means you will spray puffs of ketamine solution into each of your nostrils or take one or two troches or disintegrating tablets of ketamine under your tongue and allow them to dissolve. The intranasal ketamine solution is absorbed into the nasal mucosa in under a minute while the ketamine troches or the disintegrating tablets dissolve over several minutes and the ketamine is absorbed into the veins beneath the tongue and the lining of the cheek and the inner parts of the lips. Before starting this process, you should be in a quiet and safe location free of distractions to allow you to experience the effect of the ketamine free of stress. You should be seated or lying down reclined. During and immediately after this process, you may feel drowsy, experience changes in your heart rate or breathing, or notice changes in your balance. After the treatment, you will need time to recover and rest. You should not schedule anything physically strenuous or mentally taxing the rest of the day. For major depressive disorder and bipolar depression, current research supports using intranasal ketamine at low doses (20-30 mg) daily for several weeks or twice weekly for four weeks followed by once weekly for four weeks at higher doses (80-100 mg). For sublingual ketamine, research supports 8 treatments over a four-week period followed by maintenance treatments occurring about once a week or less frequently as clinically justified.



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What Safety Precautions Must You Take?

- You may not eat 4 hours before the treatment. You may drink water, apple juice or clear broth, up to an hour before the treatment. Please note that coffee with cream or milk is considered a meal. You may drink black coffee for up to an hour before the treatment.
- You may NOT drive a car, operate hazardous or powered equipment, or engage in hazardous activities for 12 hours after each treatment as reflexes may be slow or impaired. If you decided to have your treatment at our office, another adult will need to drive you home and must be present prior to your discharge.
- You must refrain from alcohol 24 hours prior-to and following ketamine administration. You must refrain from other illegal substances during your sublingual ketamine treatment.
- You must tell the clinic about all medications you are taking, especially narcotic pain relievers, benzodiazepines, barbiturates and muscle relaxers.
- The effect of ketamine on the fetus is unknown and it may be harmful. Notify your treating provider if you could be pregnant.
- If you experience a problem while you are at home, you should contact either the Clinic, your medical provider, or call 911. In case of an emotional crisis, you may call the National Crissi Hotline at 988.

What are the possible Side Effects of Ketamine?

Possible side effects may include but are not limited to:

- fast or irregular heartbeat
- increased or decreased blood pressure
- vivid dreams
- confusion
- irritation or excitement
- floating ("out-of-body") sensation
- twitching, muscle jerks, muscle tension
- urinary frequency



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Rare side effects of ketamine are:

- allergic reaction
- tongue, cheek or lip numbness, tingling or burning
- increase in pressure inside the eye
- inflammation in the bladder
- respiratory complications
- increased saliva or thirst
- lack of appetite
- headaches
- metallic taste
- constipation
- blurry or double vision
- nausea or vomiting
- memory change
- hallucination
- euphoria
- involuntary eye movements
- low mood or suicidal thoughts
- aspiration
- dizziness
- trouble with balance, walking or steadiness

Treatment of Potential Side Effects

If you become anxious or uncomfortable you may be offered a sedative agent (lorazepam) (trade name Ativan) if you are in our clinic; but typically, all that is needed is reassurance.

If you experience nausea, you may be offered ondansetron (trade name Zofran) or promethazine (trade name Phenergan) if you are in our clinic.



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For elevated blood pressure, you may be offered clonidine (trade name Catapres).

For elevated heart rate, or tachycardia, you may be offered propranolol (trade name Inderal).

Alternatives to Ketamine

No other procedure is available to produce the specific effect ketamine provides, although electroconvulsive therapy, transcranial magnetic stimulation, magnetic e-resonance therapy, vagal nerve stimulation, and deep brain stimulation are alternatives that may offer improvements in major depressive disorder or bipolar depression. Major depressive disorder and bipolar disorder are optimally treated with a combination of medications and psychotherapy. Specific medication treatment alternatives include monoamine oxidase inhibitors or augmentation of anti-depressants with anti-psychotics, thyroid hormone, or lithium.

Important Notices and Agreements:

SUBLINGUAL KETAMINE THERAPY IS NOT A COMPREHENSIVE TREATMENT FOR DEPRESSION, ANXIETY OR ANY PSYCHIATRIC SYMPTOMS

- Your sublingual ketamine is meant to augment (add on to, not be used in place of) comprehensive psychiatric treatment. Therapy is a highly recommended adjunct.

Initial

- While receiving sublingual ketamine, you agree to remain under the care of a qualified primary care or mental health provider and have your overall health care directed by him or her. You agree to be free of the use of any illicit substances and be free of alcohol abuse.

Initial

- You agree to follow all the instructions given to you by your ketamine provider. If in the clinic for treatment, you agree to remain at the location of the session until the provider decides you are ready to leave. The length of the ketamine session in the clinic is usually 1 to 2 hours.

Initial

- Psychiatric illnesses carry the risk of suicidal ideation (thoughts of ending one's life) or thoughts of harming others. Psychiatric illnesses may contribute to suicide attempts or violence. Any such thoughts or behaviors require immediate attention and call for help. In case of any safety risks such as these, you will call 911 or seek evaluation at your nearest emergency room.

Initial



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My Consent for Ketamine Treatment is Voluntary:

My desire for intranasal and/or sublingual ketamine treatment as described in this document is entirely voluntary and I have not been offered any inducement to consent. I understand that I may refuse ketamine treatments at any time. Any money I have deposited for future treatments will be refunded to me if I choose not to proceed with future treatment. I have been advised that I can seek a second opinion from another provider before agreeing to have ketamine treatment and I am choosing to proceed at this time, with or without this second opinion. I have notified my mental health provider and/or primary care provider of my decision to begin ketamine therapy.

Initial

Statement of Person Giving Informed Consent:

- I have read this consent form and understand the information contained in it. I understand the risks and benefits and had the opportunity to have my questions answered to my satisfaction.
- I have had the opportunity to ask questions about this procedure. I consent and would like to proceed with intranasal and/or sublingual ketamine treatment.
- I agree that the clinic may communicate with me via their app, email and text with information regarding appointments and treatments.

I understand and agree to the above:

Patient name:

Date:

Signature:

The provider treating my symptoms of depression or anxiety or other psychiatric symptoms is:

Name:

Phone:

Address: