

SUFentanil/ Ketamine nasal spray CII

60 mcg/mL SUFentanil +
60 mg/mL Ketamine

Nasal spray, solution.
Single-use device (2 mL).

Label and cap color: Green



Description

Fixed-combination nasal spray. Each 50 microliter (mcL) actuation delivers 3 micrograms (mcg) SUFentanil and 3 milligrams (mg) Ketamine. The device is configured for up to two doses for a single patient.

Composition

Active ingredients (per mL)
SUFentanil (as SUFentanil Citrate) 60 mcg, Ketamine (as Ketamine Hydrochloride) 60 mg.

Inactive ingredients
Sodium Phosphate Dibasic, Anhydrous, Sodium Phosphate Monobasic, Monohydrate, Sterile Water for Injection. Sodium Hydroxide and/or Hydrochloric Acid may be used to adjust pH between 4.6 to 5.6.

Storage

Store product in an upright position protected from light at controlled room temperature.

Do not use this medicine after the expiration date. Discard after use or within four (4) hours of opening.

Administration

For administration by a healthcare professional in a medically monitored setting only. No self-administration. See Instructions for Use on page 2.

Caution - Strength verification

Do not directly compare dose strengths with other SUFentanil or Ketamine products. Before use, verify the device has a green cap and a green border around the label. A different strength of this product is supplied in a purple-capped device.

Manufacturer

STAQ Pharma, Inc
14135 East 42nd Ave, Unit 50
Denver, CO 80239
Tel.: 833-397-0106

NDC: 73177-0172-49

In case of adverse event, please report to one or any of the following:

- www.fda.gov/medwatch
- 1-800-FDA-1088
- STAQ Pharma at 833-397-0106

Table 1. Solution Volume Remaining in Device After Dose Administration

Green cap		Strength: SUFentanil 60 mcg/mL + Ketamine 60 mg/mL; 0.05 mL (50 µL) per spray		
Dosing Guidance		Dose (mL)	Volume Remaining After Dosing (mL)	
Patient weight (kg)	Number of Sprays per Dose		After 1 ST Dose	After 2 ND Dose
10 to 14.9 kg	2	0.10	1.75	1.65
15 to 19.9 kg	3	0.15	1.70	1.55
20 to 29.9 kg	4	0.20	1.65	1.45

Table 2. Drug Content Remaining in Device After Dose Administration

Green cap		Strength: SUFentanil 60 mcg/mL + Ketamine 60 mg/mL; 0.05 mL (50 µL) per spray				
Dosing Guidance		Dose (mL)	SUFentanil (mcg)		Ketamine (mg)	
Patient weight (kg)	Number of Sprays per Dose		After 1 ST Dose	After 2 ND Dose	After 1 ST Dose	After 2 ND Dose
10 to 14.9 kg	2	0.10	105	99	105	99
15 to 19.9 kg	3	0.15	102	93	102	93
20 to 29.9 kg	4	0.20	99	87	99	87

The following information is intended for healthcare professionals only:

Instructions for Use

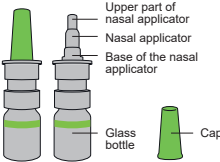
Read these Instructions for Use in full before administering SUFentanyl/Ketamine.

SUFentanyl/Ketamine is to be administered by a healthcare professional in a medically monitored setting only.

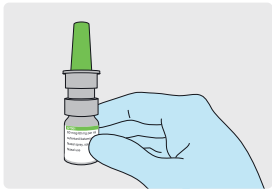
No self-administration allowed.

SUFentanyl/Ketamine is for nasal use. Each bottle of SUFentanyl/Ketamine nasal spray is to be used to administer up to two doses for a single patient.

The nasal spray consists of the following parts:



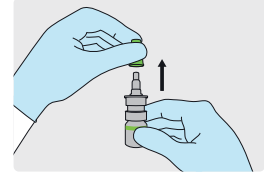
Step 1: Confirm



Confirm absence of contraindications and product concentration

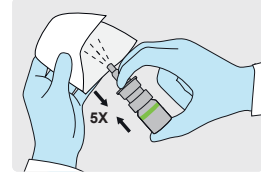
1. Confirm patient has no contraindications for SUFentanyl/Ketamine.
2. Verify that the nasal spray has a green cap and a green border around the label and the product name is SUFentanyl citrate 60 mcg/mL Ketamine HCl 60 mg/mL.
3. Confirm dose according to Table 3 in step 3.

Step 2: Prepare



Prepare the nasal spray

1. Remove the cap.
- Do not** throw away the cap. The cap will be placed back on the nasal spray after use.
- Caution:** Keep the cap out of reach of the patient at all times.



Priming – Prior to first dose only
DO NOT re-prime SUFentanyl/Ketamine prior to an additional dose.

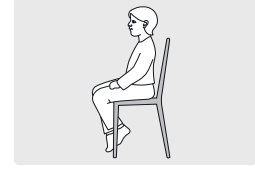
1. Move to a well-ventilated area away from the patient and others.
2. Point SUFentanyl/Ketamine into a tissue away from your face.
3. Prime SUFentanyl/Ketamine 5 times by pressing and releasing the base of the nasal spray applicator.

Do not exceed 45° angle.

Caution: Prevent inhalation of the medication by yourself or others while priming.

Note: At the first priming you may not see medication be expelled out of the applicator. At the last 2-3 primings you should see medication be expelled out. Continue to prime a total of 5 times.

Step 3: Administer first dose



Administer SUFentanyl/Ketamine

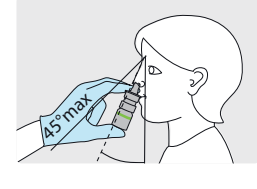
1. Seat the patient facing you with the head vertical.

For small children, it is recommended to seat the child on the lap of the parent or guardian.

Table 3. Example of dosing table used in clinical trials

[CTgov/NCT06364072](#) and [CTgov/NCT04897750](#) for Sufentanyl/Ketamine nasal spray

Table 3 Green cap		
SUFentanyl 60 mcg/mL + Ketamine 60 mg/mL; 0.05 mL (50 µL) per spray		
Weight	Number of sprays per dose	Dose administered
10 to 14.9 kg	2 sprays: 🚿🚿	6 mcg SUFentanyl 6 mg Ketamine
15 to 19.9 kg	3 sprays: 🚿🚿🚿	9 mcg SUFentanyl 9 mg Ketamine
20 to 29.9 kg	4 sprays: 🚿🚿🚿🚿	12 mcg SUFentanyl 12 mg Ketamine



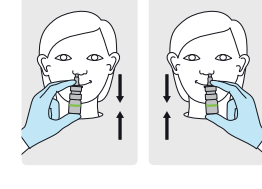
Correct angle

1. Insert the upper part of the nasal applicator into the middle of the nostril to ensure that the patient will receive the recommended dose of SUFentanyl/Ketamine.

2. Hold the nasal spray parallel to the nasal bridge.

Do not exceed 45° angle.

Do not point the applicator towards the side of the nostril.



Deliver the dose

1. Instruct the patient to breathe normally.
2. Press and release the base of the nasal spray to deliver one spray.
3. Switch to the other nostril to deliver another spray.
4. If the dose requires an additional spray, continue alternating between nostrils until the full dose is delivered.
5. Monitor for signs of sedation, respiratory depression, or reduced peripheral oxygenation.

Do not deliver the full dose in the same nostril as this will result in fluid overflow and incomplete absorption.

Note: If the medication sprays outside of the patient's nose, a new spray should be delivered.

Step 4: Reassess and administer potential second dose



Reassess the patient after first dose

1. Reassess the patient's pain level 15 minutes after the first dose.
2. If adequate analgesia has not been achieved within 15 minutes after the first dose, administer one additional dose which consists of 2-4 sprays depending on weight (see Table 3). Use the same nasal spray for the second dose.
3. Remove the cap from the nasal spray.
4. Administer the same number of sprays given in the first dose (see Table 3).



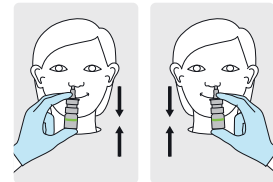
Correct angle

1. Hold the nasal spray parallel to the nasal bridge.

Do not re-prime SUFentanyl/Ketamine.

Do not exceed 45° angle.

Do not point the applicator towards the side of the nostril.



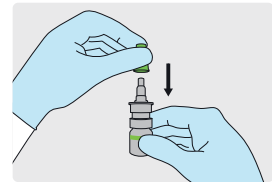
Deliver the dose

1. Instruct the patient to breathe normally.
2. Press and release the base of the nasal spray to deliver one spray.
3. Switch to the other nostril to deliver another spray.
4. If the dose requires additional spray(s), continue alternating between nostrils until the full dose is delivered.
5. Monitor for signs of sedation, respiratory depression, or reduced peripheral oxygenation.

Do not deliver the full dose in the same nostril as this will result in fluid overflow and incomplete absorption.

Note: If the medication sprays outside of the patient's nose, a new spray should be delivered.

Step 5: Dispose



Dispose SUFentanyl/Ketamine

1. Place the cap back on the nasal spray.
2. Dispose SUFentanyl/Ketamine in accordance with local requirements.

Note: Keep the nasal spray out of reach of the patient at all times.