About the Kovanaze™ Intranasal Delivery System

Kovanaze™ is indicated for regional anesthesia when performing a restorative procedure on Teeth 4-13 and A-J in adults and children who weigh 40 kg or more.

Gather Supplies from the Box Stored in the Refrigerator:

- 2X Prefilled Sprayers
- 2X Finger Grips

Storage Information

Store Kovanaze™ sprayers in a refrigerator between 36 to 46°F (2 to 8°C), with brief excursions permitted between temperatures of 32 and 59°F (0 and 15°C). Protect from prolonged exposure to ambient light prior to use.

Warnings and Important Notes

DO NOT use if drug is left out at room temperature for more than 5 days.

DO NOT use on children who weigh less than 40 kg.

DO NOT inject Kovanaze™.

DO NOT spray in the mouth.

DO NOT spray in the eye.

DO NOT re-use or refill device.

DO NOT use a cartridge warmer.

DO NOT submerge in water.

DO NOT immerse in or wipe with disinfectant or any solution.

DO NOT autoclave.

DO NOT use if dropped.

Dosing Information

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
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<tbody>
<tr>
<td>Adults (≥18 years old)</td>
<td>2 sprays + 3rd if needed</td>
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<tr>
<td>Children who weigh 40 kg or more</td>
<td>2 sprays</td>
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Understanding Where to Apply the Sprays

The sprays must be administered into the nasal cavity on the same side (ipsilateral) as the planned dental procedure. The first spray must be horizontal at approximately a 90° angle and the second spray must be at approximately a 45° angle, as illustrated below.

Check Prefilled Sprayer Solution* and Expiration Date on Carton and Sprayer Label

Check that the solution is clear and colorless.

*NOTE: The presence of a bubble is NORMAL and does NOT interfere with product or dosing.

DO NOT expel air bubble prior to dosing patient.

DO NOT use if:
- expired.
- if the solution is cloudy, discolored, or contains crystals.
- the sprayer barrel is cracked, chipped or broken.
- the tip is cracked or broken.
- the rubber cap is missing.
- the sprayer is dropped.
- the solution is frozen.

Understand the Prefilled Sprayer Parts

Assembled Prefilled Sprayer Example:

- Removable Grey Rubber Cap
- White Spray Tip
- Finger Grip
- Plunger Rod
- Glass Lip

*NOTE: The Finger Grip comes separately and must be attached prior to dosing.

Spray Position for First Spray (Approximately Horizontal)

Spray Position for Second Spray (Approximately 45 Degree Angle)

STEP 1: Gather and Assemble Supplies

1A Gather Supplies from the Box Stored in the Refrigerator:

1B Check Prefilled Sprayer Solution* and Expiration Date on Carton and Sprayer Label

1C Install Finger Grip

1D Remove the Grey Cap

STEP 2: Position Patient Upright

2 Have the dental chair and patient sitting upright. Sit on the same side as the planned dental procedure and face the patient.

Dose from the front of the patient on the same side as the planned dental procedure.

EXP: Mo. / Yr.
Position the Prefilled Sprayer Horizontal into Nostril

Place the white tip of the Prefilled Sprayer inside the nostril up to the edge of the nasal valve.

Prepare Second Prefilled Sprayer

Stabilize the Prefilled Sprayer (Examples Below)

Depress Plunger Rod as Fast as Possible

PUSH HARD AND FAST on the plunger rod. Expel the spray in ½ second or less.

Wait 4 Minutes

Spray Position 2 (Approximately 45 Degree Angle)

Position the Prefilled Sprayer tip approximately 45 degrees above the horizontal plane.

Direct the sprayer toward the middle of the nasal cavity.

Before the second spray, wait 4 minutes before continuing to Step 5.

Important Notes

After administering Kovanaze™ a single procedure can only be done on one side of the mouth. Wait at least 24 hours, or until there is complete resolution of the block, whichever is longer, before starting another procedure with Kovanaze™.

In order to ensure efficacy, wait the appropriate length of time after each dose before continuing to the next step.

DO NOT ADMINISTER A THIRD SPRAY TO CHILDREN UNDER 18 YEARS OLD.

Sprayer is for single dose use. Dispose of all used sprayers.

DO NOT re-use an activated spray device.

The solution has no smell and will feel like a light mist of water.

How long will the patient will feel numb?

In a clinical trial with Kovanaze™, the median duration of a dental procedure successfully completed with Kovanaze™ was 11 minutes, although one successfully completed dental procedure was as long as 43 minutes.

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How can I tell if the spray was not properly administered?

If the sprayer is not actuated quickly enough, liquid could drip from the nostril, stream onto the back of the patient's throat, or stay in the device.

NOTE: A small drop from the nostril sometimes occurs with proper technique.

Do children and adolescent patients receive the same dose as adults?

No. For children under 18 years old, do not administer the optional third spray that adults can receive.

What if the adult patient feels pain at the start of the dental procedure after the second spray?

Prepare a third sprayer and follow the directions in Step 7 (same as second spray).

DO NOT administer a third spray to patients under 18 years old.

What will the patient feel during the spray?

The solution has no smell and will feel like a light mist of water.

QUESTIONS? Call 1-800-865-4925

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