

KOVANAZE[®]

(tetracaine HCl and oxymetazoline HCl)

IMPORTANT FACTS ABOUT KOVANAZE[®] KOVANAZE[®] (tetracaine HCl and oxymetazoline HCl) Nasal Spray

WHAT IS KOVANAZE[®] USED FOR?

KOVANAZE[®] (tetracaine HCl and oxymetazoline HCl) Nasal Spray provides anesthesia for restorative dental procedures on the upper front ten teeth in adults and children who weigh 88 lbs (40 kg) or more.

KOVANAZE[®] has not been studied in children under 3 years of age.

WHO SHOULD NOT RECEIVE KOVANAZE[®]?

You should not receive KOVANAZE[®] if you are sensitive or allergic to tetracaine, benzyl alcohol, other ester local anesthetics, p-aminobenzoic acid (PABA), oxymetazoline, or any other component of the product. Serious allergic reactions have been associated with some of the ingredients in KOVANAZE[®]. If an allergic reaction occurs, seek emergency help immediately.

WHAT SHOULD I TELL MY DENTAL PROFESSIONAL BEFORE RECEIVING KOVANAZE[®]?

Tell your dental professional about all of your medical conditions, including if you:

- have glucose-6-phosphate dehydrogenase deficiency (G6PD) or have higher than normal levels of methemoglobin in your blood (methemoglobinemia)
- have heart or lung compromise of any kind
- have uncontrolled high blood pressure or inadequately controlled active thyroid disease of any type
- have a history of frequent nose bleeds
- are pregnant or plan to become pregnant. It is not known if KOVANAZE Nasal Spray can harm your unborn baby.
- are breastfeeding or plan to breastfeed. KOVANAZE[®] Nasal Spray can pass into your breast milk and it is not known if KOVANAZE[®] can harm your baby.

Manufactured for:

St. Renus, LLC, Fort Collins, CO 80526

KOVANAZE is a registered trademark of St. Renus, LLC.

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WHAT OTHER MEDICATIONS MIGHT INTERACT WITH KOVANAZE[®]?

Tell your dental professional about all the medicines you take, including prescription and over-the-counter medicines. Especially tell your dental professional if you take any drugs that may cause methemoglobinemia when used with KOVANAZE[®] (including nitrates/nitrites, local anesthetics, antineoplastic agents, antibiotics, antimalarials, anticonvulsants, and other drugs such as acetaminophen, metoclopramide, quinine and sulfasalazine), monoamine oxidase inhibitors (MAOIs), nonselective beta-blockers, or antidepressants.

You should stop taking products containing oxymetazoline (such as Afrin[®]) 24 hours prior to administration of KOVANAZE[®].

Avoid using other nasally-delivered products with KOVANAZE[®].

WHAT ARE THE POSSIBLE SIDE EFFECTS OF KOVANAZE[®]?

Use of local anesthetics may cause methemoglobinemia, a serious condition that must be treated promptly. Seek immediate medical attention if you or someone in your care experiences the following signs or symptoms: pale, gray, or blue colored skin (cyanosis); headache; rapid heart rate; shortness of breath; lightheadedness; or fatigue.

KOVANAZE[®] may increase blood pressure.

The most common side effects of KOVANAZE[®] include runny nose, nasal congestion, nasal discomfort, sore throat, and watery eyes.

These are not all of the possible side effects of KOVANAZE[®]. Talk to your dental professional for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

WHERE CAN I FIND MORE INFORMATION ABOUT KOVANAZE[®]?

This information is not comprehensive. To learn more, talk with your dental professional about KOVANAZE[®].

The FDA-approved product labeling can be found at www.kovanaze.com/PI or by calling 1-800-770-9400.