

KOVANAZE[®]

(tetracaine HCl and oxymetazoline HCl)

INDICATION AND IMPORTANT SAFETY INFORMATION FOR CONSUMERS

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

Indication: KOVANAZE[®] 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.

Important Safety Information: Use of local anesthetics may cause methemoglobinemia, a serious condition that must be treated promptly. KOVANAZE[®] may increase blood pressure and is not recommended if you have uncontrolled high blood pressure or thyroid disease. Allergic or anaphylactic reactions can occur. You should not receive KOVANAZE[®] if you have a known hypersensitivity to any of its ingredients or other ester local anesthetics. Tell your dentist about all medications you are taking, especially drugs that may cause methemoglobinemia when used with KOVANAZE[®], MAOIs, nonselective beta blockers or tricyclic antidepressants, and if you have a history of frequent nose bleeds. Avoid use with other nasally-delivered products and stop taking oxymetazoline-containing products 24 hours prior to your dental procedure. Common side effects include runny nose, nasal congestion, nasal discomfort, sore throat, and watery eyes. Find full prescribing information at www.kovanaze.com/PI.

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.