ONSET®

SODIUM BICARBONATE, 8.4%
pH Buffer Solution

Rx only

Volume 1.7 mL per cartridge 1.7 mEq (1 mEq/mL)

DESCRIPTION

Onset Sodium Bicarbonate, 8.4% pH Buffer Solution is a sterile, non- pyrogenic, solution of sodium bicarbonate ($NaHCO_3$) in Water. Onset is mixed with local anesthetic outside of the body for the sole purpose of adjusting the anesthetic to a more physiological pH prior to use.

The solution contains no bacteriostat or antimicrobial agent.. pH is between 7.0 and 8.5. Osmolar concentration is 2mOsmol/mL (calc.).

Sodium bicarbonate, 84 mg/mL is equal to one milliequivalent (mEq) each of Na^+ and HCO_3^-.

Sodium Bicarbonate is chemically designated as $NaHCO_3$.

Onset Sodium Bicarbonate, 8.4% pH Buffer Solution is comprised of water (H_20) and sodium bicarbonate ($NaHCO_3$). Onset Sodium Bicarbonate, 8.4% pH Buffer Solution is mixed with local dental anesthetic solution by mixing the two solutions together, outside the body prior to injecting the pH buffered local dental anesthetic, such that the $NaHCO_3$ interacts with the hydrochloric acid to raise the local dental anesthetic's pH prior to injection. During this in vitro (outside the body) mixing process, the $NaHCO_3$ is mixed with the HCl in the presence of H_2O and dissociates into CO_2 and chemical substances already present in the local anesthetic (NaCl and H_2O) according to the following chemical equation: $NaHCO_3 + HCl \rightarrow H_2O + NaCl + CO_2$. When mixed with the local anesthetic, Onset Sodium Bicarbonate, 8.4% pH Buffer Solution raises the pH of the local anesthetic without changing the chemical makeup of the anesthetic. After mixing the Onset Solution with the local anesthetic, $NaHCO_3$ is not present as an excipient or separate constituent or ingredient in the buffered local dental anesthetic injection.

USAGE

Sodium Bicarbonate, 8.4% pH Buffer Solution is mixed with commercial preparations of Lidocaine w/Epinephrine solution or other local anesthetics outside the body in order to raise the pH of the local anesthetic to a more physiologic pH prior to use.

DOSAGE

The practitioner should choose a volume of Sodium Bicarbonate, 8.4% pH Buffer Solution to be mixed with Lidocaine w/Epinephrine or other local anesthetics in an appropriate ratio of local anesthetic solution to sodium bicarbonate solution.

The below table provides a mixing guide showing for convenience the volumes of 8.4% Sterile Sodium Bicarbonate pH Buffer Solution to be added to the commercial preparations of Lidocaine with Epinephrine in order to achieve a desired ratio.

Anesthetic-to-Bicarbonate Solution Ratio Mixing Guide

Desired Ratio for 1.8 mL cartridge	Volume (mL) 8.4% Sodium Bicarbonate Solution
10:1	0.18 mL
15:1	0.12 mL
20:1	0.09 mL
30:1	0.06 mL

CONTRAINDICATIONS

Not for use as a systemic alkalizer. Not for direct injection into the body.

Onset Sodium Bicarbonate, 8.4% pH Buffer Solution mixed with local dental anesthetic has the same Contraindications in patients as local dental anesthetic alone; namely patients with a known history of hypersensitivity to local anesthetics or to any components of the local anesthetic injectable formulations.

WARNINGS

Onset Sodium Bicarbonate, 8.4% pH Buffer Solution mixed with local dental anesthetic has the same Warnings in patients as anesthetic alone.

DENTAL PRACTITIONERS WHO EMPLOY LOCAL ANESTHETIC AGENTS SHOULD BE WELL VERSED IN DIAGNOSIS AND MANAGEMENT OF EMERGENCIES WHICH MAY ARISE FROM THEIR USE. RESUSCITATIVE EQUIPMENT, OXYGEN AND OTHER RESUSCITATIVE DRUGS SHOULD BE AVAILABLE FOR IMMEDIATE USE.

Please refer to the labeling of the specific local anesthetic for additional warnings.

PRECAUTIONS

Do not store local anesthetic after buffering. Administer local anesthetic solution immediately after mixing with Sodium Bicarbonate, 8.4% pH Buffer Solution.

When mixing local anesthetic solution with Sodium Bicarbonate, 8.4% pH Buffer Solution, use aseptic technique, mix thoroughly.

General

The safety and effectiveness of any local dental anesthetic delivery depends on proper dosage, correct technique, adequate precautions and readiness for emergencies. Consult standard textbooks for specific techniques and precautions for various regional anesthetic procedures.

Onset Sodium Bicarbonate, 8.4% pH Buffer Solution mixed with local dental anesthetic has the same Precautions in patients as local dental anesthetic alone. Please refer to the labeling of the specific anesthetic for additional Precautions.

Do not use unless Onset Sodium Bicarbonate, 8.4% pH Buffer Solution is clear, colorless, and free of particulates or cloudiness, and the container or seal is intact. Do not use if the inner or outer packaging are damaged. Discard unused portion.

Once cartridge septum is pierced by transfer device or needle, the cartridge should not be removed and reinserted, to preserve the sterile path.

Do not use local anesthetic mixed with Onset Sodium Bicarbonate, 8.4% pH Buffer Solution unless the mixed solution is clear, colorless, and free of particulates or cloudiness.

Parenteral drug products should be inspected visually for particulate matter, cloudiness and discoloration prior to administration, whenever solution and container permit.

DRUG INTERACTIONS

Sodium Bicarbonate Solution and Lidocaine w/Epinephrine are compatible. See Compatibility section under Sodium Bicarbonate in *The Handbook on Injectable Drugs* by Lawrence A. Trissel, 14th ed. 2007 (American Society of Health-System Pharmacists, Bethesda, MD).

ADVERSE REACTIONS

Adverse Reactions following the administration of local dental anesthetic mixed with Onset Sodium Bicarbonate, 8.4% pH Buffer Solution are similar to those observed in patients receiving local dental anesthetic alone.

These adverse experiences are, in general, dose-related and may result from high plasma levels of anesthetic (which may be caused by excessive dosage, rapid absorption, unintended intravascular injection or slow metabolic degradation), injection technique, volume of injection, hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Please refer to the labeling of the specific local anesthetic for a detailed listing of known reactions.

Persistent pain at the site of injection is the most common complication of local anesthesia in the oral cavity. Trismus is also a relatively common complication following local anesthetic administration.

A small number of cases involving paresthesia, pain, swelling, severe swelling, lock jaw, numbness, dry mouth, soreness and trismus, and tissue necrosis have been reported following the administration of local dental anesthetic mixed with Onset Sodium Bicarbonate, 8.4% pH Buffer Solution.

To report SUSPECTED ADVERSE REACTIONS, Please contact Onpharma customer care at 1-877-336-6738, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

Adding a volume of Sodium Bicarbonate, 8.4% pH Buffer Solution to local dental anesthetic solution or other local anesthetics such that the pH of the local dental anesthetic, or other local anesthetic, is raised above physiologic pH may cause anesthetic to precipitate out of solution, reducing the clinical effectiveness of the anesthetic. See, e.g., Mulroy MF, *Regional Anesthesia, An Illustrated Procedural Guide*, 3rd Ed. 2002 (Lippincott Williams and Wilkins, Philadelphia, PA). In addition, solutions that contain precipitate should not be injected.

Adding a volume of Sodium Bicarbonate, 8.4% pH Buffer Solution to local dental anesthetic, or other local anesthetic, such that the pH of the local dental anesthetic or other local anesthetic is raised well above (7.8) physiologic pH, may cause tissue irritation when the solution is injected. See Whitcomb M, et. al., *A Prospective Randomized, Double Blind Study of the Anesthetic Efficacy of Sodium Bicarbonate Buffered 2% Lidocaine with 1:100,000 Epinephrine in Inferior Alveolar Nerve Blocks*, Anesth Prog, vol. 57, p 59 (2010).

HOW SUPPLIED

Sodium Bicarbonate, 8.4% pH Buffer Solution is supplied in 1.7 mL cartridges, in a four-cartridge package.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).

Manufactured for:
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