SODIUM BICARBONATE INJ., 8.4% USP NEUTRALIZING ADDITIVE SOLUTION

Rx only
Volume 2.7 mL per cartridge 2.7 mEq (1mEq/mL)
Volume 1.7 mL per cartridge 1.7 mEq (1mEq/mL)

DESCRIPTION:
Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution is a sterile, nonpyrogenic, solution of sodium bicarbonate (NaHCO₃) in Water for Injection. It is added to an appropriate local anesthetic as a neutralizing agent immediately prior to administration.

The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for single-use. pH is adjusted with carbon dioxide. Per the USP monograph for Sodium Bicarbonate Inj., pH is between 7.0 and 8.5. Osmolar concentration is 2mOsmol/mL (calc.).

Sodium bicarbonate, 84 mg is equal to one milliequivalent each of Na⁺ and HCO₃⁻.

Sodium Bicarbonate, USP is chemically designated as NaHCO₃, a white crystalline powder soluble in water. Sodium bicarbonate in water dissociates to sodium (Na⁺) and bicarbonate (HCO₃⁻) ions.

Sodium (Na⁺) is the principal cation of the extracellular fluid and plays a large part in hastening onset of analgesia and reducing injection pain, by adjusting commercial preparations of Lidocaine w/ Epinephrine to a more physiologic pH.

The practitioner should choose a volume of Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution to be added to common commercial preparations of Lidocaine w/ Epinephrine in order to achieve a mixed ratio of 10:1.

10:1 Anesthetic-to-Bicarbonate Solution Ratio

Mixing Guide for 10:1:

| Volume (mL), Lidoctaine w/ Epinephrine | 8.4% Sodium Bicarbonate Solution |
| Container Type | (mL) | (mL) |
| 1.8 mL (Cartridge) | 0.18 mL | 1.62 mL |
| 20 mL (Vial) | 2.0 mL | 18.0 mL |
| 30 mL (Vial) | 3.0 mL | 27.0 mL |
| 50 mL (Vial) | 5.0 mL | 45.0 mL |

CONTRAINDICATIONS:
For not use as a systemic alkaliizer.

WARNINGS:
None known.

PRECAUTIONS:
Administer local anesthetic solution immediately after combining with Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution.

When combining local anesthetic solution with Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution, use aseptic technique, mix thoroughly, and do not store.

Do not use unless Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive 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.

Do not use local anesthetic combined with Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution unless the combined 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 Inj., 8.4% USP Neutralizing Additive 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).

Pregnancy Category C
Animal reproduction studies have not been conducted in which Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution was evaluated. Animal reproduction studies have not been conducted in which Lidocaine w/ Epinephrine that has been pH adjusted by the addition of Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution was evaluated.

It is not known whether Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution can cause fetal harm when administered to a pregnant woman or whether it can affect reproduction capacity. It is not known whether Lidocaine w/ Epinephrine that has been pH adjusted by the addition of Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution can cause fetal harm when administered to a pregnant woman or whether it can affect reproduction capacity.

ADVERSE REACTIONS:
None known.

OVERDOSAGE:
Adding a volume of Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution to Lidocaine w/ Epinephrine solution such that the pH of the Lidocaine w/ Epinephrine 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 & Wilkins, Philadelphia, PA). In addition, solutions that contain precipitate should not be injected.

Adding a volume of Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution to Lidocaine w/ Epinephrine solution such that the pH of the Lidocaine w/ Epinephrine 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 Inj., 8.4% USP is supplied in 2.7 mL or 1.7 mL single-dose cartridges, packaged in a four-cartridge package.

Store at 20°-25°C (68°-77°F). (See USP.)

REFERENCES, INDICATIONS AND USAGE:


REFERENCES, DOSAGE:


Manufactured For Onpharma Company, Carson City, NV 89706
Customer Care Center: (877) 336-6738

NDC 50509-100-01
NDC 50509-100-03