SODIUM BICARBONATE- sodium bicarbonate solution
Onpharma, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

---------

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 2 mOsmol/mL (calc.).

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

Sodium Bicarbonate, USP is chemically designated as NaHC03, a white crystalline powder soluble in water. Sodium bicarbonate in water dissociates to provide sodium (Na+) and bicarbonate (HCO3-) ions.

Sodium (Na+) is the principal cation of the extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. Bicarbonate (HCO3-) is a normal constituent of body fluids and the normal plasma level ranges from 24 to 31 mEq/liter. Bicarbonate anion is considered “labile” since at a proper concentration of hydrogen ion (H+) it may be converted to carbonic acid (H2CO3) and thence to its volatile form, carbon dioxide (CO2) excreted by the lung. Normally a ratio of 1:20 (carbonic acid; bicarbonate) is present in the extracellular fluid. In a healthy adult with normal kidney function, practically all the glomerular filtered bicarbonate ion is reabsorbed; less than 1% is excreted in the urine.

Non-neutral parenteral solutions with a low (acidic) pH are known to cause chemical irritation of tissues.

INDICATIONS AND USAGE:
Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution is indicated to hasten onset of analgesia and reduce injection pain, by adjusting commercial preparations of Lidocaine w/ Epinephrine anesthetic solution to a more physiologic pH.

The practitioner should choose a volume of Sodium Bicarbonate Inj., 8.4% USP Neutralizing Additive Solution to be mixed with Lidocaine w/ Epinephrine in a ratio of 1:10 (local anesthetic solution to sodium bicarbonate solution).

The below table provides a mixing guide showing for convenience the volumes of 8.4% Sodium Bicarbonate Neutralizing Additive Solution to be added to the commercial preparations of Lidocaine with Epinephrine in order to achieve a mixed ratio of 10:1.

10:1 Anesthetic-
to-Bicarbonate Solution Ratio Mixing Guide for 10:1
<table>
<thead>
<tr>
<th>Volume (mL), Lidocaine w/ Epinephrine (container type)</th>
<th>Volume (mL), 8.4% Sodium Bicarbonate Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.8 mL (cartridge)</td>
<td>0.18 mL</td>
</tr>
<tr>
<td>20 mL (Vial)</td>
<td>2.0 mL</td>
</tr>
<tr>
<td>30 mL (Vial)</td>
<td>3.0 mL</td>
</tr>
<tr>
<td>50 mL (Vial)</td>
<td>5.0 mL</td>
</tr>
</tbody>
</table>

**CONTRAINDICATIONS:**
Not for use as a systemic alkalizer.

**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 and 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 Inc., Los Gatos, CA 95030
Customer Care Center: (877) 336-6738

NDC 50509-100-01
NDC 50509-100-03
Copyright © 2011 Onpharma Inc. All Rights Reserved (11/2011) LS013-D

1.7 mL Vial Carton Image:

1.7 mL Vial Label Image:
SODIUM BICARBONATE
sodium bicarbonate solution

Product Information
Product Type: HUMAN PRESCRIPTION DRUG
Route of Administration: PARENTERAL
Item Code (Source): NDC:50509-100

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM BICARBONATE (UNII: 8MDF5V39QO)</td>
<td>SODIUM BICARBONATE</td>
<td>84 mg in 1 mL</td>
</tr>
</tbody>
</table>

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:50509-100-02</td>
<td>4 in 1 CARTON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>NDC:50509-100-01</td>
<td>2.7 mL in 1 CARTRIDGE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:50509-100-04</td>
<td>4 in 1 CARTON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:50509-100-03</td>
<td>1.7 mL in 1 CARTRIDGE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Marketing Information
Marketing Category: unapproved drug other
Marketing Start Date: 07/22/2010

Labeler - Onpharma, Inc. (011848357)

Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>WuXi AppTec, Inc.</td>
<td></td>
<td>136584468</td>
<td>manufacture(50509-100)</td>
</tr>
<tr>
<td>Establishment</td>
<td>Name</td>
<td>Address</td>
<td>ID/FEI</td>
</tr>
<tr>
<td>---------------</td>
<td>-----------------------------</td>
<td>---------</td>
<td>----------</td>
</tr>
<tr>
<td></td>
<td>Avrio Biopharmaceuticals, LLC</td>
<td></td>
<td>829688899</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Establishment</th>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alliance Medical Products, Inc</td>
<td></td>
<td>102688657</td>
<td>manufacture(50509-100)</td>
</tr>
</tbody>
</table>

Revised: 1/2014

Onpharma, Inc.