Neut®

4% SODIUM BICARBONATE ADDITIVE SOLUTION

To adjust acidic parenteral solutions to a more nearly neutral pH.
Fliptop Vial

Rx Only

(0.2 g in 5 mL)

DESCRIPTION

Neut (4% sodium bicarbonate additive solution) is a sterile, nonpyrogenic solution of sodium bicarbonate in water for injection. It is administered by the intravenous route only after addition as a neutralizing agent to an acidic large volume parenteral solution. Each 5 mL contains sodium bicarbonate 0.2 g (2.4 mEq each of Na^+ and HCO_3^-); edetate disodium, anhydrous 10 mg added as a stabilizer. Total sodium (Na^+) content of each 5 mL is 56.1 mg (11.2 mg/mL).

The solutions contain no bacteriostat, antimicrobial agent or added buffer; pH 8.0 (7.0 to 8.5).

Sodium Bicarbonate, USP is chemically designated as $NaHCO_3$, a white crystalline powder soluble in water.

CLINICAL PHARMACOLOGY

The acid pH of most intravenous solutions has been implicated as a factor in the production of postinfusion (chemical) phlebitis not caused by obvious infection. Vein irritation, with local redness and tenderness near the site of venipuncture or along the course of a vein, appears to be related to the nature of the substances in the infusion and the speed (insufficient dilution by the bloodstream) as well as the duration (prolonged exposure of the intima) of infusion. Other contributing factors include the size of the vein used for venipuncture, shape or method of insertion of the venipuncture needle, the use or type of indwelling catheter, infection at the infusion site and the age of the patient (children and females seem to be more susceptible).

The pH of commonly used dextrose infusion solutions ranges from 3.5 to 6.5. Other commonly used solutions also may have an acid pH. Since non-neutral parenteral solutions with a low (acid) pH are known to cause chemical irritation of tissues, it is not surprising that chemical phlebitis may occur as a complication with their infusion. Vein irritation is most likely when the duration of infusion is long or when hemodilution is minimized by a large needle in a small vein.

The amount of sodium bicarbonate recommended as an additive to neutralize acid parenteral solutions is too small to exert a clinically significant increase in electrolyte content.

INDICATIONS AND USAGE

Neut (4% sodium bicarbonate additive solution) is indicated for use as an additive to raise the pH of acid solutions administered intravenously to reduce the incidence of chemical phlebitis and patient discomfort due to vein irritation at or near the site of infusion.

CONTRAINDICATIONS

Not for use as a systemic alkalizer.

WARNINGS

None known.

PRECAUTIONS

Do not administer unless solution is clear and seal is intact. Discard unused portion.

Solutions prepared with Neut (4% sodium bicarbonate additive solution) should be administered promptly. When introducing additives, use aseptic technique, mix thoroughly and do not store.

When Neut is added to Hospira solutions, the compatibility of these solutions with other drugs may be altered. (See section on COMPATIBILITY, etc., for listing of additives tested with Neut added D5-W.)

Raising the pH of I.V. fluids with Neut will only reduce the incidence of chemical irritation caused by the infusate; it will not diminish any foreign body effects caused by the needle or catheter.

Pregnancy: Animal reproduction studies have not been conducted with sodium bicarbonate. It is also not known whether sodium bicarbonate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium bicarbonate should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

None known.

DRUG ABUSE AND DEPENDENCE

None known.

OVERDOSAGE

None known.

DOSAGE AND ADMINISTRATION

One vial (5 mL) of Neut added to a liter (1000 mL) of any of the following Hospira parenteral solutions will increase the pH to a more physiologic range. Specific pH may vary slightly from lot to lot.

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

Product	**List**
5% Alcohol in 5% Dextrose Injection, USP	1500
2.5% Dextrose Inj., USP	1508
5% Dextrose Inj., USP	1522
10% Dextrose Inj., USP	1530
20% Dextrose Inj., USP	1535
Ringer's Injection, USP	1582
0.9% Sodium Chloride Inj., USP	1583
Sodium Lactate Inj., USP (1/6 Molar)	1587

Addition of one vial of Neut to one-half liter (500 mL) is recommended to achieve a more physiologic pH of the following Hospira parenteral solutions:

Product	**List**
6% Dextran 70 and 0.9% Sodium Chloride Injection	1505
6% Dextran 70 and 5% Dextrose Injection	1507

Note: Some products, e.g., Aminosyn® solutions and those Ionosol® and Normosol® formulas containing dextrose will NOT be brought to near physiologic pH by the addition of Neut. This is due to the relatively high buffer capacity of these fluids.

COMPATIBILITY & EFFECTIVENESS OF NEUT WITH ADDITIVES TO 5% DEXTROSE INJECTION (D5-W)

When medications are added to intravenous solutions, the resultant admixtures may or may not be compatible in solutions containing Neut (4% sodium bicarbonate additive solution).

Following is a list of medications each added to one liter of 5% Dextrose Injection, USP (D5-W) classified according to their effect with Neut (4% sodium bicarbonate additive solution).

1. Neut Compatible with Admixtures for 24 Hours	**Conc./liter**
ACTHAR® (ACTH)	40 units
Aqua-Mephyton® (Vitamin K_1)	10 mg
Aramine® (metaraminol) Bitartrate	100 mg†
Atropine Sulfate	0.4 mg
Calcium Chloride	1 g
Calcium Gluceptate	1.1 g
Compazine® (prochlorperazine) Edisylate	10 mg
Crystodigin® (digitoxin)	0.2 mg
Demerol® (meperidine) HCl	100 mg
Ergonovine Maleate	0.2 mg
Erythrocin® (erythromycin) Lactobionate	1 g
Fungizone® (amphotericin B)	50 mg
Ilotycin® (erythromycin) Gluceptate	1 g
Innovar® (droperidol and fentanyl)	1.0 mL
Keflin® (cephalothin) Sodium	4 g
Lidocaine HCl	1 g
M.V.I.® (multivitamin infusion)	10 mL†
Neosynephrine® (phenylephrine) HCl	10 mg
Panheparin® (heparin sodium)	20,000 units
Penicillin G Potassium	100,000,000 units
Pitocin® (oxytocin)	5 units
Potassium Chloride	120 mEq
Sodium Iodide	1 g
(promazine) HCl	100 mg
Vancocin® (vancomycin) HCl	500 mg
Wydase® (hyaluronidase)	150 units

†Requires 2 vials of Neut to bring admixture to approximate neutrality.

2. Neut Incompatible – Additive Inactivated at Neutral pH	**Conc./liter**
Epinephrine	4 mg
Isuprel® (isoproterenol) HCl	1 mg
Levophed® (levarterenol) Bitartrate	8 mg
Quelicin® (succinylcholine chloride)	1 g

3. Neut Ineffective - Additive High in Titratable Acidity	**Conc./liter**
Achromycin® (tetracycline) HCl	500 mg
Aureomycin® (chlortetracycline) HCl	500 mg
Bejectal w/C (B complex and C)	10 mL
Kantrex® (kanamycin) Sulfate	1 g

4. Neut Not Indicated –

Admixture Already At or Near Neutrality	**Conc./liter**
Gantrisin® (sulfisoxazole) Diethanolamine	4 g
Hydrocortone® (hydrocortisone) Phosphate	100 mg
Prostaphlin® (oxacillin) Sodium	500 mg
Sodium Bicarbonate	3.75 g
Solu-Cortef ® (hydrocortisone sodium succinate)	250 mg

5. Neut Not Indicated –

Admixture Already Alkaline	**Conc./liter**
Aminophylline	500 mg
Amytal® (amobarbital) Sodium	500 mg
Dilantin® (diphenylhydantoin) Sodium	250 mg
Diuril® (chlorothiazide)	0.5 g
Emivan® (ethimivan)	2 g
Furadantin® (nitrofurantoin) Sodium	180 mg
Nembutal® (pentobarbital) Sodium	500 mg
Pentothal® (thiopental sodium)	1 g
Phenobarbital Sodium	320 mg
Polycillin® N (ampicillin sodium)	500 mg
Sulfadiazine Sodium	1 g

It should be noted that the admixtures were evaluated for physical compatibility, not for pharmacological compatibility. It, therefore, would be erroneous to circumvent medical judgment which must be involved in administering any solution that appears to be compatible on the basis of having no visible haze or precipitate. The inclusion of drugs in this study of their compatibility in solution does not imply their therapeutic usefulness or safety. This matter remains the judgment of the prescribing physician.

NOTE: The compatibility information contained herein is based on the studies involving Hospira dextrose only. Variations in compatibility could occur due to lot-to-lot variations or formula changes in the additives or dextrose solutions of other manufacturers.

HOW SUPPLIED

Neut (4% sodium bicarbonate additive solution) is supplied in partial-fill single-dose containers 5 mL fliptop vial. Unit of Sale is a Tray containing 25 vials (NDC: 0409-6609-02).

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

Hospira

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