American Regent Introduces Sodium Phosphates Injection, USP; FDA-Approved and "AP" Rated[1]

Sodium Phosphates Injection, USP is available in three presentations

Shirley, NY – July 2, 2024: American Regent announces the launch and availability of Sodium Phosphates Injection, USP, which is FDA-approved and therapeutically equivalent to Sodium Phosphates.[1] Sodium Phosphates Injection, USP 3 mM P/mL is indicated as a source of phosphorus, for addition to large volume intravenous fluids, to prevent or correct hypophosphatemia in patients with restricted or no oral intake. It is also useful as an additive for preparing specific parenteral fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions.

The concomitant amount of sodium (Na^+ 4 mEq/mL) must be calculated into total electrolyte dose of such prepared solutions.

Sodium phosphate is contraindicated in diseases where high phosphorus or low calcium levels may be encountered, and in patients with hypernatremia.

"An important part of our company's mission is to assist in mitigating shortages and ensuring supply of critical medications whenever possible. To that end, we are pleased to add Sodium Phosphates Injection, USP to our robust line of products that are formulated, filled, and finished at our US-based manufacturing facilities," stated Joann Gioia, Vice President and Chief Commercial Officer at American Regent, Inc.

This product is available for immediate shipment. Customers can order Sodium Phosphates Injection, USP through their wholesaler/distributor, or by contacting our Customer Support Group at 1-800-645-1706.

Sodium Phosphates Injection, USP is supplied as follows:

NDC#	Strength Pack	Supplied as	Shelf pack
0517-7305-25	15 mM P/5 mL (3 mM P/mL) containing 20 mEq Na^+/5 mL (4 mEq/mL)	5 mL Single-dose, plastic vial	25
0517-7315-25	45 mM P/15 mL (3 mM P/mL) containing 60 mEq Na^+/15 mL (4 mEq/mL)	15 mL Single-dose, plastic vial	25
0517-7350-25	150 mM P/50 mL (3 mM P/mL) containing 200 mEq Na^+/50 mL (4 mEq/mL)	50 mL Single-dose, plastic vial	25

See the following Important Safety Information, in addition to the product's Full Prescribing Information.
For additional information, please visit www.americanregent.com

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F 631.924.1731 \\ www.americanregent.com
A Daiichi Sankyo Group Company

Sodium Phosphates Injection, USP

FOR ADDITIVE USE ONLY AFTER DILUTION IN I.V. FLUIDS

INDICATIONS AND USAGE

Sodium Phosphates Injection, USP 3 mM P/mL is indicated as a source of phosphorus, for addition to large volume intravenous fluids, to prevent or correct hypophosphatemia in patients with restricted or no oral intake. It is also useful as an additive for preparing specific parenteral fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions.

The concomitant amount of sodium (Na^+ 4 mEq/mL) must be calculated into total electrolyte dose of such prepared solutions.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Sodium phosphate is contraindicated in diseases where high phosphorus or low calcium levels may be encountered, and in patients with hypernatremia.

WARNINGS

Sodium Phosphates Injection, USP 3 mM P/mL must be diluted and thoroughly mixed before use.

To avoid phosphorus intoxication, infuse solutions containing sodium phosphate slowly. Infusing high concentrations of phosphorus may result in a reduction of serum calcium and symptoms of hypocalcemic tetany. Calcium levels should be monitored.

Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention.

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS

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

Phosphorus replacement therapy with sodium phosphate should be guided primarily by the serum phosphorus level and the limits imposed by the accompanying sodium (Na^+) ion.

Use with caution in patients with renal impairment, cirrhosis, cardiac failure, and other edematous or sodium-retaining states.

Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotropin.

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

Pediatric Use: The safety and effectiveness of sodium phosphate has been established in pediatric patients (neonates, infants, children, and adolescents).

Geriatric Use: An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Sodium ions and phosphorus are known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

Adverse reactions involve the possibility of phosphorus intoxication. Phosphorus intoxication results in a reduction of serum calcium and the symptoms are those of hypocalcemic tetany.

OVERDOSAGE

In the event of overdosage, discontinue infusions containing sodium phosphate immediately and institute corrective therapy to restore depressed serum calcium and to reduce elevated serum sodium levels. See WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

For additional safety information, please see Full Prescribing Information.

You are encouraged to report Adverse Drug Events to American Regent Inc. at 1-800-734-9236, or to the FDA by visiting www.fda.gov/medwatch or by calling 1-800-FDA-1088.

REF-2663

You are encouraged to report adverse drug events (ADEs) to American Regent:
T 1.800.734.9236; **E** pv@americanregent.com; **F** 1.610.650.0170

ADEs may also be reported to the FDA:
1.800.FDA.1088
or www.fda.gov/medwatch

Medical Information:
T 1.888.354.4855
(9:00 am–5:00 pm Eastern Time, Monday–Friday)
www.americanregent.com/medical-affairs

For medical information outside of normal business hours
that cannot wait until the next business day, please call 1.877.845.6371

About American Regent

American Regent, Inc.®, a Daiichi Sankyo Group company, is an industry-leading injectable manufacturer. For over 50 years, American Regent has been developing, manufacturing, and supplying quality generic and branded injectables for healthcare providers. For more than 20 years, we have been a leader in IV iron therapy.

American Regent is committed to US-based manufacturing. To that end, over the last several years we have made significant investments in expanding and modernizing our manufacturing facilities in Ohio and New York. This expansion will nearly double our capacity and allow us to better serve our customers now and in the future.

Speed counts. Flexibility matters. Reliability and quality are paramount. Because patients should never have to wait for the medications they need.

For more information, please visit www.americanregent.com.

About Daiichi Sankyo Group

Daiichi Sankyo is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology for our purpose "to contribute to the enrichment of quality of life around the world." In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases with high unmet medical needs. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation to realize our 2030 Vision to become an "Innovative Global Healthcare Company Contributing to the Sustainable Development of Society."

For more information, please visit: www.daiichisankyo.com.

Reference: 1. Orange book: Approved drug products with therapeutic equivalence evaluations. US Food & Drug Administration. Accessed April 12, 2024 .https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=018892#22110

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