Sodium Phosphate P 32 Solution Rx Only.

DESCRIPTION

Sterile, non-pyrogenic Sodium Phosphate P 32 is available for therapeutic application as an intravenous solution dosage form with a concentration of 24.8 megabecquerels (0.67 millicurie) per milliliter. The intravenous solution contains 1.6 milligrams per milliliter of sodium acetate as a buffer, 0.9% sodium chloride for isotonicity and may contain sodium hydroxide or hydrochloric acid for pH adjustment. The pH of the solution is between 5.0 and 6.0.

PHYSICAL CHARACTERISTICS

Phosphorus P 32 decays by beta emission with a physical half-life of 14.3 days.[1] The mean energy of the phosphorus P 32 beta particle is 694.9 keV.

Table 1. Principal Radiation Emission Data

Radiation	Mean Percent Per Disintegration	Mean Energy (keV)
Beta-1	100.0	694.9

EXTERNAL RADIATION

The range of the phosphorus P 32 beta particle, which has a maximum energy of 1.71 MeV, is 2.8 mm of aluminum.

To correct for physical decay of this radionuclide, the fractions remaining at selected time intervals before and after the day of calibration are shown in Table 2.

Table 2. Physical Decay Chart; Phosphorus P 32, Half-Life 14.3 days

Days	Fraction Remaining	Days	Fraction Remaining
0*	1.000	30	0.233
1	0.953	35	0.183
2	0.908	40	0.144
5	0.785	45	0.113
10	0.616	50	0.089
15	0.483	55	0.070
20	0.379	60	0.055
25	0.297		

**Calibration Day*

CLINICAL PHARMACOLOGY

Phosphorus is necessary to metabolic and proliferative activity of cells. Radioactive phosphorus concentrates to a very high degree in rapidly proliferating tissue.

INDICATIONS AND USAGE

The principal use of Sodium Phosphate P 32 is for the treatment of polycythemia vera, and it is effective for the treatment of chronic myelocytic leukemia and chronic lymphocytic leukemia. Sodium Phosphate P 32 is also used in palliative treatment of selected patients with multiple areas of skeletal metastases.

CONTRAINDICATIONS

Sodium Phosphate P 32 should not be used as a part of sequential treatment with a chemotherapeutic agent.

In polycythemia vera, Sodium Phosphate P 32 should not be administered when the leukocyte count is below 5,000/cu mm, or a platelet count is below 150,000/cu mm.

In chronic myelocytic leukemia, Sodium Phosphate P 32 should not be administered when the leukocyte count is below 20,000/cu mm.

For treatment of bone metastases it is usually not administered when the leukocyte count is below 5,000/cu mm, and platelet count is below 100,000/cu mm.

WARNINGS

This radiopharmaceutical should not be administered for intracavitary use.

Overdose of Sodium Phosphate P 32 may produce serious effects on the hemopoietic system. The blood and bone marrow should be carefully monitored at regular intervals.

[1] Kocher, David C., "Radioactive Decay Data Tables," DOE/TIC 11026, page 70 (1981).

Sodium Phosphate P 32 ordinarily does not localize in retinoblastomas.

PRECAUTIONS.

General

As in the use of any other radioactive material, care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenic potential, or whether Sodium Phosphate P 32 affects fertility in males or females.

Pregnancy Category C

Animal reproduction studies have not been conducted with Sodium Phosphate P 32. It is also not known whether Sodium Phosphate P 32 can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Sodium Phosphate P 32 should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken when a patient is being given Sodium Phosphate P 32.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

None known.

DOSAGE AND ADMINISTRATION

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Oral administration of high-specific-activity Sodium Phosphate P 32 in the fasting state may equal intravenous administration.

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

Waterproof gloves should be used during the entire handling and administration procedure.

Maintain adequate shielding during the life of the product and use a sterile, shielded syringe for withdrawing and injecting the drug.

For polycythemia vera, intravenous dosages from 37 to 296 megabecquerels (1 to 8 millicuries) are given depending upon the stage of disease and size of the patient. Repeat doses must be adjusted to individual needs.

For chronic leukemia, the individual dose is 222 to 555 megabecquerels (6 to 15 millicuries), usually administered with concomitant hormone manipulation.

RADIATION DOSIMETRY

The estimated absorbed radiation doses[2] to an average patient (70 kg) following intravenous administration of 555 megabequerels (15 millicuries) of Sodium Phosphate P 32 are shown in Table 3.

[2] Method of Calculation: "S", Absorbed Dose per Unit Cumulated Activity for Selected Radionuclides and Organs, MIRD Pamphlet #11 (1975).

TABLE 3. Absorbed Radiation Doses

	Absorbed radiation doses for 555 megabecquerels (15 millicuries)	
Tissue	grays	rads
Skeleton	9.45	945
Liver	0.93	93
Spleen	1.10	110
Brain	0.45	45
Testes	0.15	15
Ovaries	0.12	12
Total Body	1.50	150

HOW SUPPLIED

Catalog Number 461

Sodium Phosphate P 32 is supplied as a sterile, non-pyrogenic solution in single dose vials containing 185 megabequerels (5 millicuries) of phosphorus P 32. Each milliliter contains 24.8 megabecquerels (0.67 millicuries) sodium phosphate P 32 at the time of calibration, 1.6 miligrams sodium acetate and 9 milligrams sodium chloride. The solution may contain sodium hydroxide or hydrochloric acid for pH adjustment.

STORAGE AND HANDLING

Store at controlled room temperature 20-25°C (68-77°F).

Storage and disposal of Sodium Phosphate P 32 Solution should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of this radionuclide.

The U.S. Nuclear Regulatory Commission has approved distribution of this radiopharmaceutical to persons licensed to use byproduct material listed in Section 35.300, and to persons who hold an equivalent license issued by an Agreement State.

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