Phosphocol® P 32

Chromic Phosphate P 32 Suspension
Rx Only.

Therapeutic—For Interstitial or Intracavitary Use Only

DESCRIPTION
Phosphocol® P 32 is supplied as a sterile, nonpyrogenic aqueous suspension in a 30% dextrose solution with 2% benzyl alcohol added as preservative. Each milliliter contains 1 mg sodium acetate. Sodium hydroxide or hydrochloric acid may be present for pH adjustment.

ACTIONS
Local irradiation by beta emission.

INDICATIONS
Phosphocol P 32 is employed by intracavitary instillation for the treatment of peritoneal or pleural effusions caused by metastatic disease, and may be injected interstitially for the treatment of cancer.

CONTRAINDICATIONS
Chromic phosphate P 32 therapy should not be used in the presence of ulcerative tumors.

Administration should not be made in exposed cavities or where there is evidence of loculation unless the extent of loculation is determined.

WARNINGS
Not for intravascular use.

This radiopharmaceutical should not be administered to patients who are pregnant or during lactation unless the therapeutic benefits outweigh the potential hazards.

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

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.

Careful intracavitary instillation is required to avoid placing the dose of chromic phosphate P 32 into intrapleural or intraperitoneal loculations, bowel lumen or into the body wall. Intestinal fibrosis or necrosis and chronic fibrosis of the body wall have been reported to result from unrecognized misplacement of the therapeutic agent.

The presence of large tumor masses indicates the need for other forms of treatment. However, when other forms of treatment fail to control the effusion, chromic phosphate P 32 may be useful. In bloody effusion, treatment may be less effective.

Pediatric Use
Safety and effectiveness in pediatric patients has not been established.

ADVERSE REACTIONS
Untoward effects may be associated with use of chromic phosphate P 32. These include transitory radiation sickness, bone marrow depression, pleuritis, peritonitis, nausea and abdominal cramping. Radiation damage may occur if accidentally injected interstitially or into a loculation.

DOSAGE AND ADMINISTRATION
The suggested dose range employed in the average patient (70 kg) is:

Intraperitoneal instillation: 370 to 740 megabecquerels (10 to 20 millicuries)

Intrapleural instillation: 222 to 444 megabecquerels (6 to 12 millicuries)

Doses for interstitial use should be based on estimated gram weight of tumor, about 3.7 to 18.5 MBq/gm (0.1 to 0.5 mCi/gm).

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

PHYSICAL CHARACTERISTICS
Phosphorus P 32 decays by beta emission with a physical half-life of 14.3 days.[1] The mean energy of the beta particle is 695 keV.

Table 1. Principal Radiation Emission Data

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

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 percentages that remain 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	Days	Fraction Remaining
-15	2.07	2	0.908	35	0.183
-10	1.62	5	0.785	40	0.144
-5	1.28	10	0.616	45	0.113
-2	1.10	15	0.483	50	0.089
-1	1.05	20	0.379	55	0.070
0*	1.00	25	0.297	60	0.055
1	0.953	30	0.233	65	0.043

*Calibration Day

RADIATION DOSIMETRY
The effective half-life of phosphorus P 32 is considered to be equal to its physical half-life, with a residence time of 495 hours.

The radiation dose from a uniformly distributed concentration of 37 kilobecquerels (1 microcurie) per gram within a 16-gram prostate is estimated to be equivalent to about 7.3 grays (730 rads). Table 3 shows the estimated radiation doses to the prostate and the pleural or peritoneal surfaces of an average patient (70 kg) from a dose of 740 megabecquerels (20 millicuries) of phosphorus P 32.

In comparison to the distribution in the prostate, the distribution of phosphorus P 32 on the pleural and peritoneal surfaces is non-uniform, with great extremes in local doses. To obtain an estimate of the average dose, the surface area of the pleural and peritoneal cavities can be assumed to amount to 4,000 and 5,000 cm^2, respectively. The estimated[2] radiation doses to an average patient (70 kg) with 90% retention of a dose of 740 megabecquerels (20 millicuries) of phosphorus P 32 distributed uniformly over these areas are shown in Table 3. The decreases of the averaged radiation doses at various tissue depths away from the surfaces of the pleural and peritoneal cavities are also tabulated.

Table 3. Estimated Radiation Doses

Surface/Organ			Pleural		Peritoneal		Prostate	
% Retention Area/wt			90 4000 cm^2		90 5000 cm^2		100 16 gm	
Depth in tissue (cm)	Dose rate* (rads/hr)	(mGy/hr)	Tissue Dose / 740 MBq (20mCi) rads	grays	rads	grays	rads	grays
0.004	10.2	102	23000	230	18000	180	910000	9100
0.008	8.58	85.8	19000	190	15000	150		
0.012	7.61	76.1	17000	170	14000	140		
0.016	6.91	69.1	15000	150	12000	120		
0.020	6.36	63.6	14000	140	11000	110		
0.10	2.41	24.1	5400	54	4300	43		
0.20	0.94	9.4	2100	21	1700	17		

*For surface deposition of 37 kBq(1 μCi)/ cm^2

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

[2] Estimated radiation doses shown in Table 3 are based on compilations by Cross, William G., Table of Beta Dose Distribution, Report AECL 2793 Chalk River, Ontario, November 1967.

HOW SUPPLIED

Catalog Number 470

Phosphocol P 32 - Chromic Phosphate P 32 Suspension (NDC No. 0019-N470-P0) is available in 10 milliliter vials containing 555 megabecquerels (15 millicuries) with a concentration of 185 megabecquerels (5 millicuries) per milliter. The radiopharmaceutical is manufactured with a specific activity of 122 megabecquerels (3.3 millicuries) per milligram Chromic Phosphate at the time of standardization.

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.

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

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Mallinckrodt Inc.
St. Louis, MO 63134

MALLINCKRODT

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PHOSPHOCOL® P 32 CHROMIC PHOSPHATE P 32 SUSPENSION

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