P32 SODIUM PHOSPHATE - p32 sodium phosphate injection, suspension AnazaoHealth Corporation

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.

P32 Chromic Phosphate Suspension

DESCRIPTION

AnazaoHealth's compounded P32 Chromic Phosphate is supplied as a sterile, nonpyrogenic aqueous solution. It contains 30 % dextrose solution, 1 mg sodium acetate, 2 % benzyl alcohol added as a preservative. Sodium hydroxide or hydrochloric acid may be added for pH adjustment.

INDICATIONS AND USAGE

P32 chromic phosphate is indicated for intracavitary instillation for the treatment of peritoneal or pleural effusions caused by metastatic disease, and may be injected interstitially for the treatment of cancer. It is also used in hemophilia patients for intraarticular injections.

Mechanism of Action

Radioactive phosphorous works by local irradiation by beta emission.

CONTRAINDICATIONS

P32 sodium phosphate should not be used in the presence of ulcerative tumors.

WARNINGS

Not for intravascular injection.

DOSAGE AND ADMINISTRATION

Shake the vial well before injection.

For intraperitoneal instillation, administer 10-20 mCi

For intrapleural instillation, administer 6 to 12 mCi

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

DECAY CHART

To use the decay table find the number of days in the top row and left hand column of the chart then find the corresponding decay factor. To obtain a precalibration number, divide by the decay factor. For a postcalibration number multiply by the decay factor.

Days	0	1	2	3	4	5	6	7	8	9
0	1.00	.953	.908	.865	.824	.785	.748	.712	.679	.646
10	.616	.587	.559	.532	.507	.483	.460	.439	.418	.398
20	.379	.361	.344	.328	.312	.298	.284	.270	.257	.245
30	.234	.223	.212	202	.192	.183	.175	.166	.158	.151

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1

P32 Chromic Phosphate Suspension 15 mCi/mL 3mL

Dextrose 0.3 g/mL Sodium Acetate 1 mg/mL

 Benzyl Alcohol 0.02 mL/mL

 Lot:
 Cal:

 Exp:

 Pharmacy Compounded
 Sterile, non-pyrogenic for injection



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P32 SODIUM PHOSPHATE

p32 sodium phosphate injection, suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51808- 127
Route of Administration	INTRA-ARTICULAR, INTRAPERITONEAL, INTERSTITIAL, INTRAPLEURAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PHOSPHORUS P-32 (UNII: 690284A407) (PHOSPHORUS P-32 - UNII:690284A407)	PHOSPHORUS P-32	5 mCi in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DEXTROSE (UNII: IY9XDZ35W2)	0.3 g in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.02 mL in 1 mL
SODIUM ACETATE (UNII: 4550K0SC9B)	1 mg in 1 mL

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51808-127-01	3 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/19/2012	

Labeler - AnazaoHealth Corporation (011038762)

Establishment

Name	Address	ID/FEI	Business Operations
Anazao Health Corporation		011038762	MANUFACTURE(51808-127)

Revised: 6/2012

AnazaoHealth Corporation