P32 SODIUM PHOSPHATE - p32 sodium phosphate solution
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 Sodium Phosphate

Dear Medical Professional,

Per your order, we have compounded P32 Sodium Phosphate as a sterile intravenous solution dispensed in a 10 mL plastic vial with a total volume of 4 mL. The characteristics of this preparation are described below.

DESCRIPTION

AnazaoHealth's compounded P32 sodium phosphate vial is a sterile, non-pyrogenic radiopharmaceutical. The intravenous solution contains 0.25 N sodium acetate buffer, which is made of 0.9% sodium chloride and 0.09% sodium phosphate dibasic, and is compounded to a total volume of 4 mL. The pH of the solution is between 5 and 6.

INDICATIONS AND USAGE

P32 sodium phosphate is indicated for the treatment of polycythemia vera and is effective for the treatment of chronic myelocytic leukemia and chronic lymphocytic leukemia. It may also be used in the palliative treatment of selected patients with multiple areas of skeletal metastases

Mechanism of Action

Radioactive phosphorous concentrates to a very high degree in rapidly proliferating tissues

CONTRAINDICATIONS

P32 sodium phosphate should not be used as part of a sequential treatment with a chemotherapeutic agent. It should not be administered when the leukocyte count is below 5,000/cu mm or a platelet count that is below 150,000/cu mm.

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

For the 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

DOSAGE AND ADMINISTRATION

For polycythemia vera, intravenous dosages from 1 to 8 mCi are usually given depending upon the stage of disease and the size of the patient. Repeat doses must be adjusted to individual needs. For chronic leukemia, the individual dose is 6 to 15 mCi, usually administered with concomitant hormone manipulation

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1

P32 Sodium Phosphate 10 mCi 4mL

Sodium Acetate Buffer

Lot # **Cal:** **Exp:**

Pharmacy Compounded Sterile, non-pyrogenic for injection

5710 Hoover Blvd., Tampa, FL 33634
Phone (800) 995-4363 Fax (800) 697-5250

P32 SODIUM PHOSPHATE

p32 sodium phosphate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51808-128
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHOSPHORUS P-32 (UNII: 690284A407) (PHOSPHORUS P-32 - UNII:690284A407)	PHOSPHORUS P-32	10 mCi in 4 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM ACETATE (UNII: 4550K0SC9B)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51808-128-01	4 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
AnazaoHealth Corporation		011038762	MANUFACTURE(51808-128)