^{32}P sodium phosphate

^{32}P sodium phosphate is only available with a doctor's statement.

1. Indications
Treatment of:
- Polycythaemia vera (PV)
- Essential Thrombocythaemia (ET)
- Bone pain associated with skeletal metastases

2. Preparation
Supplied as solution destined for direct oral or intravenous administration to the patient in aliquots varying in activity depending on therapeutic application.

3. Quality control
European Pharmacopeia
pH: 6-8

Phosphates
Maximum 89 µg/MBq
Test solution: dilute the preparation to be examined with water to give a radioactive concentration of 370 kBq of ^{32}P per ml. Mix in a volumetric flask, with shaking, 1,0 ml of this solution with a mixture of 0,5 ml of ammonium molybdate solution, 0,5 ml of a 2,5 g/l solution of ammonium vanadate and 1ml of perchloric acid, and dilute to 5,0 ml with water.
Reference solution: Prepare at the same time and in the same manner as the test solution, using 1,0 ml of a solution containing 33 mg of orthophosphate ion per ml.
After 30 min, the test solution is not more intensely colored than the reference solution.

Radionuclide purity
Beta-ray spectrometry
Spectrum does not differ significantly from that obtained with ^{32}P-solution

Radiochemical purity ^{32}P Phosphate
Ascending paper chromatography
Test solution: dilute the preparation to be examined with water until the radioactivity is equivalent to 10.000-20.000 counts per min per 10 µl.
Reference solution: a solution of phosphoric acid containing 2 mg of phosphorus per ml.
Paper: pure cellulose grade thin paper (for example Whatman). Use a strip of paper 25 mm wide and about 300 mm long.

Mobile phase: mixture of 0,3 ml of ammonia, 5 g of trichloroacetic acid, 25 ml of water and 75 ml of 2-propanol.
Application: 10 µl of the reference solution, then apply to the same point of application 10 µl of the test solution.
Development: for 16 h.
Drying: in air.
Detection: spray with 50 g/l solution of perchloric acid and then with a 10 g/l solution of ammonium molybdate. Expose the paper to hydrogen sulfide. A blue colour develops. Determine the distribution of radioactivity using a suitable detector.
Limit: ^{32}P phosphate: ≥95%.

4. Contraindications
Total white cell count <2,0x10^{9}/l
Pregnancy
Rapidly deteriorating renal function

5. Interactions
Chemotherapy and radiotherapy
With respect to the adverse effect on bone marrow, ^{32}P Sodium phosphate should not be administered simultaneously with chemotherapy or radiotherapy.

Oestrogen and androgen preparations
The use of oestrogen and androgen preparations may affect the metabolism and retention of labelled phosphorus ^{32}P.

6. Adverse reactions
Leukopenia and thrombocytopenia.
Incidence of leukemia is increased in patients with ^{32}P and varies between 2% and 15% at 10 years. This risk is similar to chemotherapy.

7. Biodistribution & pharmacokinetics
During the first 3 days after intravenous injection of sodium phosphate ^{32}P, this radiopharmaceutical is distributed uniformly within the phosphate pool throughout the body. After 3 days, sodium phosphate ^{32}P is deposited primarily in the bone marrow, liver and spleen. About 85% of the administered dose localizes to bone because of its high inorganic phosphorous content. The liver also accumulates the agent due to its high phosphorous turnover rate.
Only 5-10% is excreted in the urine during the first 24 h and approximately 20% during the first week. Although 90% of the agent is filtered by the glomeruli, 85-90% is reabsorbed primarily in the proximal tubule. Whole blood studies using PV patients indicated two-compartment pharmacokinetics with mean half-lives of 1,7 and 22,5 days. The biological half-life in bone marrow varied from 9-27 days depending on the bone.

8. Stability
The shelf life for this product is 14 days from the date of manufacture. Store at room temperature.

9. Literature:

- Tennvall J, Brans B, EANM procedure guideline for 32P phosphate treatment of myeloproliferative diseases. Eur J Nucl Med Mol Imaging (2007) 34:1324-7.
- National Academies; Health effects of project shad chemical agent: phosphorous-32 5radiotoxic effects); spring 2004.
- SmPC 32P-Sodium orto-phosphate for injection.