

Product specification **P-32 Sodium orto-phosphate injection**

Radiochemical purity	> 99.0
Radionuclide purity	> 99.5 %
pH	6.0 – 7.0

Pharmacological properties

After injection the soluble radiophosphate is concentrated by rapidly proliferating tissue. The blood cells precursors in the bone marrow divide and proliferate rapidly in health and even more so in these diseases. The radionuclide P-32 present in sodium orthophosphate-P-32 selectively concentrates in the mitotically active cells of the bone marrow and in trabecular and cortical bone.

Radiation dosimetry

Phosphorus – P-32 is a beta emitter ($E_{\max} = 1,71$ MeV) with a physical half-life of 14,29 days. According to ICRP model, a fraction of 0.30 of intravenously administered activity is assumed to go to mineral bone and to be permanently retained, and 0.70 is assumed to be distributed in soft tissues.

Phosphorus metabolism is complex. Activity deposited in soft tissues is assumed to be rapidly eliminated from the body (30%) and about 40% of activity possesses a 19-day biological half-life, the remaining 30% is reduced by radioactive decay. The high-energy beta emissions can present a substantial skin dose hazard.

The effective dose equivalent at adult patient (70kg) after administration of P-32 Sodium orthophosphate is 2.20 mSv/MBq. The radiation dose absorbed in breast is about 0.92 mGy/MBq, in the bone marrow 11.0 mGy/MBq and in bone surfaces about 11.0 mGy/MBq. In other organs, the absorbed radiation doses are lower (0.74 mGy/MBq).

Lifetime

14 days from the reference day.

Storage

Store at room temperature, 5 – 25 °C, in accordance with regulations pertaining to health safety from ionizing radiation.

Type of package

Radiopharmaceutical is delivered in portions containing required activity (certified on 12:00 CET of the reference day) and volume, as ordered by the attending physician.

Special precautions

The radiopharmaceutical can be used by authorized personnel only. It must be handled with care and appropriate safety measures should be used to minimize radiation exposure of the clinical staff and the patient. The approvals for their acquisition and administration are subject to relevant national regulations.

Indications

Therapy of polycythemia vera and polythrombocytopenia and related disorders, leukemia and other neoplastic haematological disorders and in diagnosis for certain ocular tumors. Palliative treatment of painful bone metastasis from prostate, breast, lung and other carcinomas is reported but its myelotoxicity should be considered.

Dosage

The preparation is destined for direct oral or intravenous administration to the patient in aliquots varying in activity depending on therapeutic application. Recommended dose is 74 – 111 MBq (2 – 3 mCi) on 1 m² of body surface but not more than 185 MBq (5 mCi) In leukemia approximately 37 – 74 MBq (1 to 2 mCi) is given weekly until the white blood cell count is sufficiently decreased.

Contraindications

If the patient's platelet count is less than 15'000 it is suggested not to administer the preparation.

Interactions

Interactions with other drugs are not known; with respect to the adverse effect of bone marrow, the product should not be administered simultaneously with chemotherapy and radiation therapy (or within a short interval after them), if the therapeutic effect does not outbalance the risk.

Pregnancy and lactation

When it is necessary to administer radioactive medicinal products to women of childbearing potential, information should always be sought about pregnancy. Breast feeding should be discontinued after administration because of the potential hazard to the suckling.

Undesirable effects

Therapy with P-32 Sodium ortho-phosphate injection gives the risk of leukemia in 2 – 15 % of patients during 10 years (similar to chemotherapy).

Overdose

The preparation is delivered in portions prepared on request with the patient activity dose calculation performed by responsible physician. Should an accidental administration of an excess of radioactive substance occur, the radiation risk can be reduced by induction of a frequent voiding.

Composition

40 – 400 MBq	of P-32 phosphoric acid
1 mg/ml	of P in sodium ortho-phosphate, Na ₂ HPO ₄ x 12 H ₂ O
0,9 mg/ml	of Sodium chloride

The product does not contain any antimicrobial additives.