for labelling with ^{166}Ho radionuclide	**SYNOPHYT** **(sodium phytate)** **kit for radiopharmaceutical preparation**

Product code: **HO-IK-27**

Marketing Authorization Number: **OGYI-T-20759/01**

Composition (per vial):

Sodium phytate	16 mg
Sodium dihydrogen phosphate dihydrate	13 mg
Sodium hydroxide	as needed

Indications: **RADIONUCLIDE THERAPY**
Radiosynovectomy, radionuclide therapy of joint synovitis

Administration: Intraartticularis injection

Labelling efficiency: > 95 %

Method of administration: This medicinal product should be reconstituted before administration to the patient.
Prior to administration, Synophyt powder must be labelled with [^{166}Ho]holmium chloride precursor to obtain [^{166}Ho]holmium phytate suspension injection. National recommended procedure for radiosynovectomy should be followed during administration.

Posology: 600 MBq of [^{166}Ho]holmium phytate is to be administered.

Contraindications:
- hypersensitivity to any of the ingredients,
- septic arthritis,
- ruptured popliteal cyst,
- local skin infection,
- severe damage of the bone or cartilage,
- extensive joint instability with bone destruction
- evidence of significant cartilage loss within the joint
- pregnancy,
- breastfeeding,
- below 18 years of age,
- intraarticular radioisotope therapy of the joint in the previous 6 months

Storage: Synophyt kit is to be stored in a fridge at 2-8°C in its original paper box protected from light and oxidising agents.
[^{166}Ho]holmium phytate suspension injection is to be stored below 25^{o}C in accordance with the regulations on radioactive materials.

Expiry time: 6 months from manufacture.

Packaging: Primary packaging material of the sterile, bacterial endotoxin-free, freeze-dried powder for solution for injection is glass vial closed with rubber stopper and aluminium cap. The labelled vials are supplied in a white carton box, which contains:
- 6 glass vials for 6 labelling procedures
- 1 Summary of Product Characteristics
- 6 empty, self-adhesive labels with radiation symbol