**SYNOPHYT**  
(sodium phytate)  
kit for radiopharmaceutical preparation

**for labelling with**  
$^{166}$Ho  
radionuclide

**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:**
- Intraarticularis 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°C in accordance with the regulations on radioactive materials.

**Expiration 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