



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 January 2018  
EMA/34229/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: technetium (99mTc) hynic-octeotide

Procedure no.: PSUSA/00010521/201706



| Product Name (in authorisation country)                                                 | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|-----------------------------------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| 99mTc-Tektrotyd, 16 mikrogramów, zestaw do sporządzania preparatu radiofarmaceutycznego | not available                | 11664                         | NARODOWE CENTRUM BADAŃ JĄDROWYCH   | PL                                       |
| Tektrotyd, 20 mikrogram, sæt til præparation af radioaktive lægemidler                  | SE/H/1509/001                | 55834                         | NARODOWE CENTRUM BADAŃ JĄDROWYCH   | DK                                       |
| Tektrotyd, 20 mikrogramm, készlet radioaktív gyógyszerkészítményekhez                   | SE/H/1509/001                | OGYI-T-23052/01               | NARODOWE CENTRUM BADAŃ JĄDROWYCH   | HU                                       |
| Tektrotyd, 20 mikrogrammi, radiofarmatseutiline komplekt                                | SE/H/1509/001                | 912916                        | NARODOWE CENTRUM BADAŃ JĄDROWYCH   | EE                                       |
| Текротид, 20 микрограма, кит за радиофармацевтичен препарат                             | SE/H/1509/001                | 20160231                      | NARODOWE CENTRUM BADAŃ JĄDROWYCH   | BG                                       |
| Tektrotyd 20 mikrogramů, kit pro radiofarmakum                                          | SE/H/1509/001                | 88/339/16-C                   | NARODOWE CENTRUM BADAŃ JĄDROWYCH   | CZ                                       |
| Tektrotyd 20 mikrogram, preparasjonssett til radioaktive legemidler                     | SE/H/1509/001                | 15-10662                      | NARODOWE CENTRUM BADAŃ JĄDROWYCH   | NO                                       |
| Tektrotyd, 20 mikrogrammaa, valmisteyhdistelmä radioaktiivista lääkettä varten          | SE/H/1509/001                | 33343                         | NARODOWE CENTRUM BADAŃ JĄDROWYCH   | FI                                       |
| Tektrotyd, 20 micrograme, kit pentru preparat radiofarmaceutic                          | SE/H/1509/001                | 9335/2016/01                  | NARODOWE CENTRUM BADAŃ JĄDROWYCH   | RO                                       |

| Product Name (in authorisation country)                                           | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|-----------------------------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| Tektrotyd, 20 mikrogramów, zestaw do sporządzania preparatu radiofarmaceutycznego | SE/H/1509/001                | 23479                         | NARODOWE CENTRUM BADAŃ JĄDROWYCH   | PL                                       |
| Tektrotyd 20 mikrogramov, s(lprava pre nidiofarmakum                              | SE/H/1509/001                | 88/0423/16-S                  | NARODOWE CENTRUM BADAŃ JĄDROWYCH   | SK                                       |
| Tektrotyd 20 mikrogram, beredningssats för radioaktiva läkemedel                  | SE/H/1509/001                | 528540                        | NARODOWE CENTRUM BADAŃ JĄDROWYCH   | SE                                       |
| TEKTROTYDE                                                                        | not available                | 77774/5-11-2012               | MEDIRAY GPC                        | GR                                       |
| TEKTROTYDE                                                                        | not available                | 77774/5-11-2012               | MEDIRAY GPC                        | GR                                       |
| Tektrotyd 16 Mikrogramm Kit für ein radioaktives Arzneimittel                     | DE/H/3726/001                | 436939                        | ROTOP PHARMAKA AG                  | AT                                       |
| TEKTROTYD 16 microgramos equipo de reactivos para preparación radiofarmacéutica   | DE/H/3726/001                | 80718                         | ROTOP PHARMAKA AG                  | ES                                       |
| Tektrotyd 16 Mikrogramm Kit für ein radioaktives Arzneimittel                     | DE/H/3726/001                | 88709.00.00                   | ROTOP PHARMAKA AG                  | DE                                       |
| TEKTROTYD 16 microgrammes, trousse pour préparation radiopharmaceutique           | DE/H/3726/001                | 34009 550 284 2 0             | ROTOP PHARMAKA AG                  | FR                                       |
| TEKTROTYD 16 micrograms kit for radiopharmaceutical preparation                   | DE/H/3726/001                | PL 41222/0001                 | ROTOP PHARMAKA AG                  | UK                                       |

| <b>Product Name (in authorisation country)</b>                   | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| TEKTROTYD 16 microgrammi, kit per preparazione radiofarmaceutica | DE/H/3726/001                       | 042375016                            | ROTOP PHARMAKA AG                         | IT                                              |
| Tektrotyd 16 µg, conjunto para preparações radiofarmacêuticas    | DE/H/3726/001                       | 5675459                              | ROTOP PHARMAKA AG                         | PT                                              |