3.1. NAME OF THE MEDICINAL PRODUCT
3.2. DOSAGE FORMS AND PACKAGING

3.3. PHARMACOLOGICAL FORM

3.4. PHARMACODYNAMIC PROPERTIES

3.5. PHARMACOTHERAPEUTIC CLASS

3.6. PHARMACEUTICAL CHEMISTRY

3.7. PHARMACEUTICAL PROPERTIES

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

4.2. Precautions and Contraindications

4.3. Contraindications

4.4. Special precautions for storage

4.5. Effects on the ability to drive and use machines

4.6. Undesirable effects

4.7. Overdose in adults and in children

5. TOXICOLOGICAL INFORMATION

6. PHARMACOLOGICAL CONSIDERATIONS

7. PHARMACOEPIDEMIOLOGICAL CHARACTERISTICS

8. PATIENT INFORMATION

9. PATIENTS WITH RENAL IMPAIRMENT

10. PATIENTS WITH HEPATIC IMPAIRMENT

11. MANUFACTURER
**9. MARKETING AUTHORISATION NUMBER**

OC-7/0541/01

**10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

18 August 1995 / 18 December 2009

**11. DATE OF REVISION OF THE TEXT**

27 July 2016

**11. DOSIMETRY**

Radioiodine intake as expressed to ICRP Publication No. 31 (1977) and ICRP Publication No. 60 (1990) is about 56%.

The ICRP model refers to intravenous administration. Since absorption of radioiodine is rapid and complete, this model is applicable in case of oral administration.

Assuming that the mean residence time in the stomach is 0.5 days, the activity might be calculated prior to administration.

The ICRP model refers to intravenous administration. Since absorption of radioiodine is rapid and complete, this model is applicable in case of oral administration.

**12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS**

Method of control of the drug

**13. INSTRUCTIONS FOR USE**

**14. POSSIBLE SIDE EFFECTS**

**15. HOW TO STORE THYROTOP**

**16. FURTHER INFORMATION**