PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Levothyroxine:

Levothyroxine, the active substance in Levothyroxine sodium, is a synthetic thyroid hormone for the treatment of diseases and dysfunctions of the thyroid gland. It has the same effect as the naturally occurring thyroid hormones.

This is a summary of the risk management plan (RMP) for Levothyroxine. The RMP details important risks of Levothyroxine, how these risks can be minimised, and how more information will be obtained about Levothyroxine's risks and uncertainties (missing information). Levothyroxine's summary of product characteristics (SmPC) gives essential information to healthcare professionals and patients on how Levothyroxine should be used.

I. The medicine and what it's used for:

Levothyroxine 25 - 200 microgram:

- Treatment of benign euthyroid goitre
- Prophylaxis of relapse after surgery for euthyroid goitre, depending on the post-operative hormone status
- Substitution therapy in hypothyroidism
- Suppression therapy in thyroid cancer

Levothyroxine 25 – 100 microgram:

- Concomitant supplementation during anti-thyroid drug treatment of hyperthyroidism

Levothyroxine 100/150/200 microgram:

- Diagnostic use for thyroid suppression testing

II. Risks associated with the medicine and activities to minimize or further characterize the risks:

Important risks of Levothyroxine, together with measures to minimize such risks and the proposed studies for learning more about Levothyroxine's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and summary of product characteristics (SmPC) addressed to patients and healthcare professionals.
- Important advice on the medicine's packaging.
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without Prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

II.A. List of important risks and missing information

Important risks of Levothyroxine are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered.

Important risks can be regarded as identified or potential. Identified risks are concerns for which there is enough proof of a link with the use of Levothyroxine. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important Identified Risks	• None
Important Potential Risks	• Circulatory collapse in very low birth weight preterm neonates
Missing Information	• None

II.B. Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C. Post authorisation Development Plan

II.C.1 Studies which are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Levothyroxine.

II.C.2 Other Studies in Post Authorisation Development Plan

There are no studies required for Levothyroxine.