Summary of risk management plan for Tirosint (Levothyroxine sodium)

This is a summary of the risk management plan (RMP) for Tirosint. The RMP details important risks of Tirosint how these risks can be minimized, and how more information will be obtained about Tirosint risks and uncertainties (missing information).

Tirosint summary of product characteristics (SmPCs) and its package leaflet give essential information to healthcare professionals and patients on how Tirosint should be used.

I. The medicine and what it is used for

Tirosint is authorized for:

- /…/ 25 - 200 micrograms soft capsulesTreatment of benign goitre with euthyroid function
- Prophylaxis against recurrent goitre after resection of a goitre with euthyroid function, depending on postoperative hormone status
- Thyroid hormone replacement in hypothyroidism
- Suppression therapy for malignant thyroid tumour
- Supportive therapy in thyrostatic treatment of hyperthyroidism
- Thyroid suppression test.

- /…/ 13 micrograms soft capsules In children as an initial dose for thyroid hormone replacement in hypothyroidism,
- In elderly patients, patients with coronary heart disease and patients with severe or chronic hypothyroidism as low initial dose which should then be increased slowly and at prolonged intervals (e.g. gradually increasing the dose by 13 µg every 14 days) with frequent monitoring of thyroid hormone values.
- In any patient requiring gradual increase of levothyroxine dose

Tirosint contains levothyroxine and it is given by oral route.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Tirosint, together with measures to minimise such are outlined below.
Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and 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 minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

Important risks of Tirosint are risks that need special risk management activities to further investigate or minimise 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 sufficient proof of a link with the use of Tirosint. 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).

II.B Summary of important risks

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

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 Tirosint.

II.C.2 Other studies in post-authorisation development plan

There are no other studies required for Tirosint.