Summary of risk management plan for Levothyroxine Orion (Levothyroxine sodium) Orion Corporation

Date: 23.11.2018, Version 1

This is a summary of the risk management plan (RMP) for Levothyroxine Orion. The RMP details important risks of the product, how these risks can be minimised, and how more information will be obtained about the product's risks and uncertainties (missing information).
Levothyroxine Orion's summary of product characteristics (SmPC) and its package leaflet give essential
information to healthcare professionals and patients on how the product should be used.
Important new concerns or changes to the current ones will be included in updates of Levothyroxine Orion's RMP.

I. The medicine and what it is used for

Levothyroxine Orion is authorised for following indications:

Levothyroxine Orion 25–150 micrograms:
- 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 Orion 25–100 micrograms:
- concomitant supplementation during anti-thyroid drug treatment of hyperthyroidism.

Levothyroxine Orion 100 - 150 micrograms:
- diagnostic use for thyroid suppression testing.

It contains levothyroxine as the active substance and it is given by mouth.

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

Important risks of Levothyroxine Orion, together with measures to minimise such risks and the proposed studies for learning more about product's risks, 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.
In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Levothyroxine Orion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

This product has no safety concerns requiring additional pharmacovigilance actions or additional risk minimisation activities.

II.B Summary of important risks

Safety concerns are adequately addressed in the product information.

II.C Post-authorisation development plan

There are no studies required for Levothyroxine Orion.