Part VI: Summary of risk management plan

Summary of risk management plan for Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutide UF, Liraglutide Tecnimede (liraglutide)

This is a summary of the risk management plan (RMP) for Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutid Teva GmbH, Liraglutide Tecnimede. The RMP details important risks of Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutid Teva GmbH, Liraglutide Tecnimede and how more information will be obtained about Liraglutide's risks and uncertainties (missing information).

Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutid Teva GmbH, Liraglutide Tecnimede's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutid Teva GmbH, Liraglutide Tecnimede should be used.

Important new concerns or changes to the current ones will be included in updates of Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutid Teva GmbH, Liraglutide Tecnimede's RMP.

I. The medicine and what it is used for

Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutid Teva GmbH, Liraglutide Tecnimede is authorised for the treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

- As monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- In addition to other medicinal products for the treatment of diabetes It contains

liraglutide as the active substance, and it is given by injection.

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

Important risks of Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutid Teva GmbH, Liraglutide Tecnimede, together with measures to minimise such 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, including PSUR assessment, 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 Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutid Teva GmbH, Liraglutide Tecnimede is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutid Teva GmbH, Liraglutide Tecnimede are risks that need special risk management activities to further investigate or minimise the risks, so that the medicinal product can be safely taken. 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 Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutid Teva GmbH, Liraglutide Tecnimede. 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 longterm use of the medicine);

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• Neoplasms (including melanoma) • Medullary thyroid cancer (C-cell carcinogenicity) • Pancreatic cancer
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 authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutid Teva GmbH, Liraglutide Tecnimede.

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

There are no studies required for Liraglutide STADA, Liraglutide Medical Valley, Nolimerin, Rondit, Glanux, Liraglutid Teva GmbH, Liraglutide Tecnimede.