Part VI: Summary of risk management plan

Summary of risk management plan for Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen (liraglutide)

This is a summary of the risk management plan (RMP) for Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen. The RMP details important risks of Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen, how these risks can be minimised, and how more information will be obtained about Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen's risks and uncertainties (missing information).

Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen should be used.

Important new concerns or changes to the current ones will be included in updates of Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen's RMP.

I. The medicine and what it is used for

Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen is authorised for the treatment of:

- In adults as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of:
  - ≥30 kg/m² (obesity), or ≥27 kg/m² to
  - <30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea

- In Adolescents (≥12 years) can be used as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescent patients from the age of 12 years and above with:
  - obesity (BMI corresponding to ≥30 kg/m2 for adults by international cut-off points) and
  - body weight above 60 kg

- Children (6 to <12 years)

Liraglutide is indicated as an adjunct to healthy nutrition and increased physical activity for weight management in children from the age of 6 to <12 years with

- obesity (BMI ≥95th percentile)* and
- body weight ≥45 kg

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 Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen, 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 the case of Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen, these measures are supplemented with *additional risk minimization measures* mentioned under relevant important risks, below.

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 Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen 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 Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen. 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	• Neoplasms (including melanoma) • Medullary thyroid cancer (C-cell carcinogenicity) • Pancreatic cancer
Missing information	• Patients with a history of major depression or other severe psychiatric disorders • Concomitant use of other weight lowering products

II.B Summary of important risks

Important potential risk: Neoplasms (including melanoma)	
Risk minimisation measures	Routine risk minimisation measures: none Additional risk minimisation measures: none
Important potential risk: Medullary thyroid cancer (C-cell carcinogenicity)	
Risk minimisation measures	Routine risk minimisation measures: *Routine risk communication:* - *Nonclinical findings are described in Section 5.3 of the SmPC* *Routine risk minimisation activities recommending specific clinical measures to address the risk:* - *A warning on thyroid disease is included in Section 4.4 of the SmPC and Section 2 of the PL* Additional risk minimisation measures: none
Important potential risk: Pancreatic cancer	
Risk minimisation measures	Routine risk minimisation measures: none Additional risk minimisation measures: none
Missing information: Patients with a history of major depression or other severe psychiatric disorders	
Risk minimisation measures	Routine risk minimisation measures: none Additional risk minimisation measures: none
Missing information: Concomitant use of other weight lowering products	
Risk minimisation measures	Routine risk communication: *the lack of data supporting data of co-administration with other products for weight management is included in Section 4.4 of the SmPC* Additional risk minimisation measures: none

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 Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen.

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

There are no studies required for Liraglutid Teva, Siluxir, Liraglutide Liconsa, Viasend, Nogluxa, Liraglutide pluspharma, Liraglutide Universal Farma, Lirmynta, Liraglutide Tecnigen.