Part VI: Summary of the risk management plan

Summary of risk management plan for Plaobes (Liraglutide solution for injection in pre-filled pen 6 mg/ml)

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

Plaobes's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Plaobes should be used.

Important new concerns or changes to the current ones will be included in updates of Plaobes's RMP.

I. The medicine and what it is used for

Adults:

Plaobes is authorised 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.

Treatment with Plaobes should be discontinued after 12 weeks on the 3.0 mg/day dose if patients have not lost at least 5% of their initial body weight.

Adolescents (≥12 years):

Plaobes 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.

Treatment with Plaobes should be discontinued and re-evaluated if patients have not lost at least 4% of their BMI or BMI z score after 12 weeks on the 3.0 mg/day or maximum tolerated dose.
It contains liraglutide as the active substance and it is given subcutaneously.

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

Important risks of Plaobes's, together with measures to minimise such risks and the proposed studies for learning more about Plaobes'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.

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

II.A List of important risks and missing information

Important risks of Plaobes's are risks that need special risk management activities to further investigate or minimise the risk, 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 Plaobes. 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

List of important risks and missing information	
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

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 Plaobes.

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

There are no studies required for Plaobes.