Part VI: Summary of the risk management plan

Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe

(Lanreotide acetate)

This is a summary of the risk management plan (RMP) for Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe. The RMP details important risks Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe, how these risks can be minimised, and how more information will be obtained about Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe 's risks and uncertainties (missing information).
Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe ‘s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe should be used.

I. The medicine and what it is used for

Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe is indicated for acromegaly, grade 1 and a subset of grade 2 gastroenteropancreatic neuroendocrine tumours of midgut, pancreatic or unknown origin and as treatement of symptoms associated with neuroendocrine (carcinoid) tumours.
Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe contains contains lanreotide as the active substance and is administered by deep subcutaneous injection in the superior external quadrant of the buttock or in the upper outer thigh.

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

Important risks of Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe, together with measures to minimise such risks and the proposed studies for learning more about Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe'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*.

II.A List of important risks and missing information

Important risks of Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe 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 Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe. 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.

List of important risks and missing information	
Important identified risks	**None**
Important potential risks	**None**
Missing information	**None**

II.B Summary of important risks

The safety information in the proposed Product Information of Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe is aligned to the reference medicinal product: Somatuline® Autogel 60 mg, 90 mg, 120 mg, solution for injection in a pre-filled syringe (Ipsen farmaceutica).

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 Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe.

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

There are no studies required for Lanreotide Viatris 60mg, 90mg and 120mg solution for injection in pre-filled syringe.