

Part VI: Summary of the risk management plan

Summary of risk management plan for Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe

This is a summary of the risk management plan (RMP) for Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe. The RMP details important risks of Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe, how these risks can be minimised, and how more information will be obtained about Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe risks and uncertainties (missing information).

Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe's should be used.

This summary of the RMP for Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe's RMP.

I. The medicine and what it is used for

Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe is indicated for acromegaly, grade 1 and a subset of grade 2 gastroenteropancreatic neuroendocrine tumours of midgut, pancreatic or unknown origin and as treatment of symptoms associated with neuroendocrine (particularly carcinoid) tumours.

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

Important risks of Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe, together with measures to minimise such risks and the proposed studies for learning more about Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe, 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.

II.A List of important risks and missing information

Important risks of Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe 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 Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled 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 (e.g. on the long-term use of the medicine).

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 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 Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe.

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

There are no studies required for Lanreotide Pharmathen 60mg, 90mg, 120mg solution for injection in a prefilled syringe.