1 Summary of the risk management plan for Norditropin

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

Norditropin's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Norditropin should be used.

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

1.1 The medicine and what it is used for

Norditropin is authorised for treatment of growth failure in children with growth hormone deficiency (GHD), girls with Turner syndrome, pre-pubertal children with chronic renal disease, children born small for gestational age (SGA) and treatment of adults with GHD (see the SmPC for the full indication). It contains somatropin as the active substance and it is given by daily subcutaneous administration. The injection site should be varied to prevent lipoatrophy.

Further information about the evaluation of Norditropin's benefits can be found in Norditropin's assessment report, available on the EMA website, under the medicine's webpage.

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

Important risks of Norditropin, together with measures to minimise such risks and the proposed studies for learning more about Norditropin'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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

1.2.1 List of important risks and missing information

Important risks of Norditropin 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 Norditropin. 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).

Table 1-1 List of important risks and missing information

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

1.2.2 Summary of important risks

This section is not applicable as there are no important risks relevant for inclusion in the risk management plan for Norditropin.

1.2.3 Post-authorisation development plan

1.2.3.1 Studies which are conditions of the marketing authorisation

No studies are conditions of the marketing authorisation or specific obligation of Norditropin.

1.2.3.2 Other studies in post-authorisation development plan

There are no studies required for Norditropin.