SANDOZ A Novartis Division

Chief Medical Office & Patient Safety

Somatropin
5, 10 and 15 mg/1.5 mL solution for injection

EP2000

Summary of the EU Safety Risk Management Plan

Active substance(s) (INN or common name):	Somatropin
Product(s) concerned (brand name(s)):	Omnitrope
Marketing authorization holder	Sandoz Pharmaceuticals AG, Rotkreuz, CH
Document status:	Final
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Disclaimer:

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Omnitrope is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Omnitrope in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Sandoz Pharmaceuticals AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Omnitrope.

Summary of the risk management plan for Omnitrope

This is a summary of the risk management plan (RMP) for Omnitrope, a biosimilar to Genotropin. Currently there are no important identified, potential risks, and missing information for Omnitrope.

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

This summary of the RMP for Omnitrope 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 Omnitrope's RMP.

I. The medicine and what it is used for

Omnitrope is a medicine used to treat infants, children, and adolescents who:

- do not grow normally because they do not have enough growth hormone;
- are short because they have long-term kidney disease or a genetic disorder called Turner syndrome;
- are short and were born small for their gestational age, and have not caught up by the age of 4 years or later;
- have a genetic condition called Prader-Willi syndrome. Omnitrope is given to improve their growth and body composition (by reducing fat and improving muscle mass). The diagnosis must be confirmed by genetic testing.

Omnitrope is also used as replacement therapy in adult patients with pronounced growth hormone deficiency. The deficiency can have started in adulthood or childhood, and needs to be confirmed by testing before treatment.

The full indications are listed in the SmPC of Omnitrope.

Omnitrope contains the active substance somatropin and is a 'biosimilar' medicine. This means that Omnitrope is highly similar to a biological medicine (the 'reference medicine') that is already authorised in the European Union (EU).

Further information about the evaluation of Omnitrope's benefits can be found in Omnitrope's EPAR, including its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's

webpage:
https://www.ema.europa.eu/en/medicines/human/EPAR/omnitrope

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Omnitrope, together with measures to minimize such risks and the proposed studies for learning more about Omnitrope's risks, are outlined below.

Measures to minimize 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, 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 Omnitrope are risks that need special risk management activities to further investigate or minimize 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 Omnitrope. 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

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-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Omnitrope.

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

There are no other studies in post-authorization development plan.