# SUMMARY OF RISK MANAGEMENT PLAN

# for

# SIGNIFOR® (pasireotide)

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| Active substance: | Pasireotide |
| Product concerned (brand name): | Signifor® |
| Marketing Authorisation Holder/Applicant name: | Recordati AG |
| RMP Version number: | EU RMP Version 8.0 |
| Data lock point for this RMP: | 24-Oct-2018 |
| Date of final sign off: | 18-Jun-2024 |

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 Signifor® 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 Signifor® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Recordati AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Signifor®.

This summary of risk management plan is prepared in alignment with the current European Risk Management Plan (RMP) for Signifor (version 8.0, dated 18-Jun-2024).

## 1. The Medicine and What it is Used for

Signifor is authorized in the following indications:

**Pasireotide sc**

Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed.

**Pasireotide long-acting**

Treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue.

Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed.

60 mg strength is only to be used in the treatment of acromegaly.

Signifor contains pasireotide as the active substance and it is administered either subcutaneously by self-injection or administered by deep intramuscular injection by a trained healthcare professional.

Further information about the evaluation of Signior's benefits can be found in Signifor's European Public Assessment Report, including in its plain-language summary, available on the European Medicines Agency website, under the medicine's webpage:
https://www.ema.europa.eu/en/medicines/human/EPAR/Signifor.

## 2. Risks associated with the Medicine and Activities to Minimise or further characterise the risks

Important risks of Signifor, together with measures to minimize such risks and the proposed studies for learning more about Signifor'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 Periodic Safety Update Report assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

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

## 2.A List of Important Risks and Missing Information

Important risks of Signifor 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 Signifor. 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).

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| **Important identified risks** | There is no important identified risk. |
| **Important potential risks** | There is no important potential risk. |
| **Missing information** | Use in pregnant and breastfeeding women. |

## 2B. Summary table of Safety Concerns

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| **Important identified risks: None** | |
| **Important potential risks: None** | |
| **Missing information: Use in pregnant and breastfeeding women** | |
| **Risk minimisation measures** | Routine risk minimisation measures<br>Pasireotide sc and pasireotide long-acting SmPC: Section 4.6 Fertility, pregnancy and lactation and SmPC Section 5.3 Preclinical safety data.<br><br>Additional risk minimization measures<br>None |
| **Additional pharmacovigilance activities** | None |

## 3. Post-authorization development plan

### 3.A Studies which are conditions of the marketing authorization

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

### 3.B Other studies in post-authorization development plan

There are no studies in post-authorization development plan of Signifor.