# PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

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| Version when Module last updated | 7.8 |

## Summary of risk management plan for ELIGARD (leuprorelin acetate)

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

The ELIGARD summary of product characteristics (SmPC) and its package leaflet (PL) provide essential information to healthcare professionals (HCPs) and patients on how ELIGARD should be used.

Important new concerns or changes to the current ones will be included in updates of the RMP for ELIGARD.

## I. The medicine and what it is used for

ELIGARD is authorized for the treatment of hormone-dependent advanced prostate cancer and for the treatment of high-risk localized and locally advanced hormone-dependent prostate cancer in combination with radiotherapy (see SmPC for the full indication). It contains leuprorelin acetate as the active substance and it is given subcutaneously. ELIGARD 7.5 mg is administered as a single subcutaneous injection every month. ELIGARD 22.5 mg is administered as a single subcutaneous injection every 3 months. ELIGARD 45 mg is administered as a single subcutaneous injection every 6 months.

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

Important risks of ELIGARD, together with measures to minimize such risks, associated with ELIGARD, 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 HCPs;
- Important advice on the medicine's packaging;
- The authorized 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 the case of ELIGARD, these measures are supplemented with *additional risk minimization measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Updated Report (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 ELIGARD 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 ELIGARD. 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 identified and potential risks and missing information** | |
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| Important identified risks | Lack of efficacy due to medication error |
| Important potential risks | None |
| Missing information | None |

## II.B Summary of important risks

| **Important identified risk: Lack of efficacy due to medication error** | |
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| Evidence for linking the risk to the medicine | This important identified risk is based on post-marketing data for ELIGARD.<br>Lack of clinical efficacy may occur due to incorrect reconstitution of the product. A cumulative review of post-marketing data identified reports of lack of efficacy due to medication error, specifically handling errors associated with improper storage, preparation, reconstitution, and/or administration of the product. |
| Risk factors and risk groups | Not applicable |
| *Table continued on next page* | |

| **Important identified risk: Lack of efficacy due to medication error** | |
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| Risk minimization measures | Routine risk minimization measures<br>• SmPC (all ELIGARD formulations) sections 4.2 Posology and method of administration<br>• SmPC (all ELIGARD formulations) 4.4 Special warnings and precautions use<br>• SmPC (all ELIGARD formulations) 6.4 Special precautions for storage<br>• SmPC (all ELIGARD formulations) 6.6 Special precautions for disposal and other handling<br><br>The PL of the concerned products is in line with the information contained in the SmPC previously described. Such information is given in the following sections of the PL:<br><br>• PL (all ELIGARD formulations) section 3 How to take<br>• PL (all ELIGARD formulations) section 5 How to store ELIGARD<br>• PL (all ELIGARD formulations) section Information for HCPs;<br><br>Other routine risk minimization measures beyond the product information: Prescription only medicine.<br><br>Additional risk minimization measures:<br>• Educational materials: poster, website, and video |

# II.C Post-authorization development plan

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

There are no studies that are conditions of the marketing authorization or specific obligation of ELIGARD.

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

There are no category 3 studies ongoing or planned.