# PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

## Summary of Risk Management Plan for Paliperidone Viatris and LODIXEON 3-months (Paliperidone)

This is a summary of the risk management plan (RMP) for Paliperidone Viatris and LODIXEON 3-months. The RMP details important risks of Paliperidone Viatris and LODIXEON 3-months, how these risks can be minimised, and how more information will be obtained about Paliperidone Viatris and LODIXEON 3-months's risks and uncertainties (missing information).

Paliperidone Viatris and LODIXEON 3-months's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

Important new concerns or changes to the current ones will be included in updates of Paliperidone Viatris and LODIXEON 3-months's RMP.

## I. The Medicine and What it is Used For

Paliperidone Viatris and LODIXEON 3-months is authorised for the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly paliperidone palmitate injectable product (see SmPC for the full indication). It contains Paliperidone as the active substance and it is given by intramuscular route.

## II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Paliperidone Viatris and LODIXEON 3-months, together with measures to minimise such 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, 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 Paliperidone Viatris and LODIXEON 3-months is not yet available, it is listed under 'missing information' below.

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

Important risks of Paliperidone Viatris and LODIXEON 3-months are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered to patients. 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 Paliperidone Viatris and LODIXEON 3-months. 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/use in special patient populations etc.)

**Table 4: Part VI.1- Summary of safety concerns**

| **List of Important Risks and Missing Information** | |
|---|---|
| Important Identified Risks | None |
| Important Potential Risks | None |
| Missing Information | Exposure during pregnancy |

## II.B Summary of Important Risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

**Table 5: Part VI.4- Missing Information: Exposure during pregnancy**

| | |
|---|---|
| **Risk Minimisation Measures** | Routine risk minimisation measures<br>• Section 4.6, Fertility, pregnancy, and lactation<br>• Section 5.3, Preclinical safety data<br><br>Additional risk minimisation measures<br>• None |

## 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 Paliperidone Viatris and LODIXEON 3-months.

### II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Paliperidone Viatris and LODIXEON 3-months.