Summary of Risk Management Plan for TREVICTA (Paliperidone Palmitate 3-Monthly Injection)

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

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

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

I. The Medicine and What It Is Used For

TREVICTA is authorized 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 administered by injection as a prolonged-release suspension in prefilled syringes containing 273, 410, 546, or 819 mg of TREVICTA; which is equivalent to 175, 263, 350, or 525 mg, respectively, of paliperidone. TREVICTA is administered by a healthcare professional.

Further information about the evaluation of TREVICTA's benefits can be found in TREVICTA's EPAR, including in 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/trevicta.

II. Risks Associated With the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of TREVICTA, together with measures to minimize such risks and the proposed studies for learning more about TREVICTA'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 PL and SmPC addressed to patients and healthcare professionals;
- 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 (eg, 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 analyzed including Periodic Safety Update Report (PSUR) 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 TREVICTA is not yet available, it is listed under "missing information" below.

II.A. List of Important Risks and Missing Information

Important risks of TREVICTA 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 TREVICTA. 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.

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

Missing Information: Exposure during pregnancy	
Risk minimization measures	**Routine risk minimization measures:** SmPCs for INVEGA, XEPLION, Paliperidone Janssen-Cilag International, and TREVICTA: Section 4.6, Fertility, pregnancy and lactation Section 5.3, Preclinical safety data **Additional risk minimization measures:** None

II.C. Postauthorization Development Plan

II.C.1. Studies Which Are Conditions of the Marketing Authorization

No studies are conditions of the marketing authorization or specific obligation for TREVICTA.

II.C.2. Other Studies in Postauthorization Development Plan

No studies are required for TREVICTA.