Summary of the Risk Management Plan

As the safety concerns and their management are identical for all products covered by this RMP, the information in Part VI is presented only once together for all products.

Summary of risk management plan for LACOSAMID ZENTIVA

This is a summary of the risk management plan (RMP) for Lacosamid Zentiva. The RMP details important risks of Lacosamid Zentiva, and how more information will be obtained about Lacosamid Zentiva's risks and uncertainties (missing information).
Lacosamid Zentiva's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Lacosamid Zentiva should be used.

I. The medicine and what it is used for

Lacosamid Zentiva is authorised as monotherapy and adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy. It contains lacosamide as the active substance and it is given orally (film-coated tablets).

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Lacosamid Zentiva, together with measures to minimise such risks and the proposed studies for learning more about Lacosamid Zentiva's 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 patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

If important information that may affect the safe use of Lacosamid Zentiva is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Lacosamid Zentiva are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Lacosamid Zentiva. 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	
Important identified risks	• Cardiac AEs that may be potentially associated with PR interval prolongation and sodium channel modulation
Important potential risks	• None
Missing information	• Use in pregnancy and lactation

II.B Summary of important risks

Use in pregnancy and lactation	
Additional pharmacovigilance activities	Additional pharmacovigilance activities: EURAP – An International Registry of Antiepileptic Drugs and Pregnancy. See section II.C of this summary for an overview of the post-authorisation development plan.

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 Lacosamid Zentiva.

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

Study Status	Summary of objectives	Safety concerns addressed	Milestones	Due dates
Category 3 - Required additional pharmacovigilance activities (by the competent authority)				
EURAP: An International Registry of Antiepileptic Drugs and Pregnancy Ongoing	The **primary objective** of the study is to evaluate and determine the comparative degree of safety of antiepileptic drugs in the human foetus, with reference to: - New and old antiepileptic drugs - Individual drugs and drugs in combinations. The **secondary objectives** of the study are to: - Establish the pattern of major malformations, if there is any, associated with antiepileptic drugs, individually and in combinations - Evaluate dose-effect relationships - Delineate drug-specific syndromes (if any). The **tertiary objectives** of the study are to provide reference data for: - Use in pre-pregnancy counselling - Development of guidelines for pre-pregnancy management and counselling.	Use in pregnancy and lactation.	Not defined.	Not defined in the protocol. Half-yearly reports prepared by the Central Project Commission shall be transferred to national coordinators and sponsors.

Study Status	Summary of objectives	Safety concerns addressed	Milestones	Due dates
	The **teratogenic endpoints** of the study are the presence or absence of: - Major malformations - Prenatal growth retardation **Evaluation of risk factors**.			

EURAP

The MAA has been asked by the Reference Member State to join the antiepileptic drug pregnancy registry EURAP in line with the reference product Vimpat in order to gain more information concerning use of lacosamide in pregnant and lactating women.

Purpose of the study: The purpose of the study is to gain more information concerning use of lacosamide in pregnant and lactating women.