Summary of the risk management plan

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

DIACOMIT summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how DIACOMIT should be used.

This summary of the RMP for DIACOMIT 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 DIACOMIT RMP.

I. The medicine and what it is used for

DIACOMIT is authorised for use in conjunction with clobazam (CLB) and valproate (VPA) as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (SMEI, Dravet syndrome) whose seizures are not adequately controlled with CLB and VPA (see SmPC for the full indication). It contains stiripentol as the active substance and it is given by oral route.

Further information about the evaluation of DIACOMIT benefits can be found in DIACOMIT'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/diacomit.

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

Important risks of DIACOMIT, together with measures to minimise such risks and the proposed studies for learning more about DIACOMIT 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 DIACOMIT is not yet available, it is listed under "missing information" below.

II. A. List of important risks and missing information

Important risks of DIACOMIT 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 DIACOMIT.

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	None
Important potential risks	None
Missing information	Use during pregnancy

II. B. Summary of important risks

Missing information: Use during pregnancy	
Risk minimisation measures	Routine risk minimisation measures: - SmPC section 4.6 - Medication under prescription only. - Medicine that needs particular surveillance during the treatment. No additional risk minimisation measures
Additional pharmacovigilance activities	Study 34 62 -7 (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 DIACOMIT.

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

Study short name: **Study 34 62 - 7**

Purpose of the study: The aim of this study is to collect information about pregnancy outcomes in women exposed to STP in routine clinical practice within 30 days of conception or during pregnancy. The specific objective is to estimate the frequency of major congenital

malformations, spontaneous abortions, stillbirths, preterm births, and small-for-gestational-age birth in women exposed to STP within 30 days of conception or during pregnancy.