Summary of Risk Management Plan for Diacomit® (stiripentol)

Document version : 2.1

Document date : 25.03.2021

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.
The RMP summary of Diacomit is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.
Please note that the reference document which is valid and relevant for the effective and safe use of Diacomit in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

Zambon Svizzera SA is fully responsible for the accuracy and correctness of the content of the published summary RMP of Diacomit.

Summary of Risk Management Plan for Diacomit (stiripentol)

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's risks and uncertainties (missing information).
Diacomit's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Diacomit should be used.

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. It contains stiripentol as the active substance and it is given by oral route.

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 amont 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 minimization measures	Routine risk minimization measures: • SmPC section 4.6 • Medication under prescription only • Medicine that needs particular surveillance during the treatment No additional risk minimization 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.