Part VI: Summary of the risk management plan

Summary of risk management plan for Valproate Life Medical 100 mg/ml solution for injection or infusion

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

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

I. The medicine and what it is used for

Valproate Life Medical is authorised for primarily generalized epileptic seizures and partial and secondarily generalized seizures (see SmPC for the full indication). It contains sodium valproate as the active substance and it is given intravenously.

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

Important risks of Valproate Life Medical together with measures to minimise such risks and the proposed studies for learning more about Valproate Life Medical'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.

In the case of Valproate Life Medical, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Valproate Life Medical are risks that need special risk management activities to further investigate or minimise 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 Valproate Life Medical . 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	- Teratogenicity
Important potential risks	- Risks to unborn children via third generation and paternal exposure
Missing information	- None

II.B Summary of important risks

Important identified risk: Teratogenicity	
Risk minimisation measures	*Routine risk minimisation measures:* SmPC sections 4.2, 4.4, 4.6, 4.8 and 5.3. Boxed warning in the beginning of PIL. PIL section 2. Visual reminder on the outer package. Legal status: Prescription-only medicine. *Additional risk minimisation measures:* Pregnancy prevention programme Healthcare Professional Guide Patient guide Direct Healthcare Professional Communication (DHPC)

Important potential risk: Risks to unborn children via third generation and paternal exposure	
Risk minimisation measures	*Routine risk minimisation measures:* SmPC section 4.6. *Additional risk minimisation measures:* Direct Healthcare Professional Communication (DHPC)

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 Valproate Life Medical.

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

There are no studies required for Valproate Life Medical.