Part VI: Summary of the risk management plan

Summary of risk management plan for clobazam 1 mg/ml oral suspension

This is a summary of the risk management plan (RMP) for Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension. The RMP details important risks of Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension, how these risks can be minimised, and how more information will be obtained about Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension's risks and uncertainties (missing information).

Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension should be used.

I. The medicine and what it is used for

Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension may be used as adjunctive therapy in epilepsy in adults and children from 6 months of age, if standard treatment with one or more anticonvulsants has failed.

It contains clobazam as the active substance and it is given by oral administration.

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

Important risks of Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension, together with measures to minimise such 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 Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension, 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, including 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 Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension 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 Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension. 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	• Serious skin reactions including Stevens-Johnsons syndrome and Toxic epidermal necrolysis • Use with alcohol • Use in special populations at risk of accumulation (elderly, impaired hepatic or renal function) • Muscle weakness • Respiratory depression • Dependence • Withdrawal syndrome • Tolerance • Psychiatric and paradoxical reactions • Interaction with anticonvulsants drugs, opioids and CNS depressants drugs • Use during pregnancy and breastfeeding (neonatal dependence and withdrawal)
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Important identified risk 5- Respiratory depression	
Risk minimisation measures	Routine risk minimisation measures SmPC section 4.2 contains information about changing between different formulations The patient's condition should be assessed throughout treatment in SmPC section 4.2 SmPC section 4.3 where use in patients with severe respiratory insufficiency are contraindicated. SmPC section 4.4 include warning of switching between formulations. SmPC section 4.4 where a warning is given not to initiate treatment in patients with severe respiratory insufficiency and to monitor patients with chronic or acute severe respiratory insufficiency. SmPC section 4.5 where interaction with alcohol is described.

Important identified risk 5- Respiratory depression	
	SmPC section 4.5 where interaction with opioids and risk of respiratory depression is described. SmPC section 4.8 listed as adverse reaction SmPC section 4.9 how overdose is manifested. SmPC section 5.2 where results for the bioequivalence study is listed PL section 2 and 4. Legal status: Prescription only medicines. Additional risk minimisation measures Distribution of DHPC letter.

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 Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension.

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

There are no studies required for Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension.