Summary of risk management plan for Phenichem 18, 27, 36, 45 and 54 mg depottablett (methylphenidate)

This is a summary of risk management plan (RMP) for Phenichem 18, 27, 36, 45 and 54 mg depottablett. The RMP details important risks of Phenichem 18, 27, 36, 45 and 54 mg depottablett, and how more information will be obtained about Phenichem 18, 27, 36, 45 and 54 mg depottablett risks and uncertainties (missing information).

Phenichem 18, 27, 36, 45 and 54 mg depottablett summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Phenichem 18, 27, 36, 45 and 54 mg depottablett should be used.

Important new concerns or changes to the current ones will be included in updates of Phenichem 18, 27, 36, 45 and 54 mg depottablett's RMP.

I. The medicine and what it is used for

Phenichem 18, 27, 36, 45 and 54 mg depottablett is authorised for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) (see SmPC for the full indication). It contains methylphenidate 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 Phenichem 18, 27, 36, 45 and 54 mg depottablett 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 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*.

II.A List of important risks and missing information

Important risks of Phenichem 18, 27, 36, 45 and 54 mg depottablett 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 Phenichem 18, 27, 36, 45 and 54 mg depottablett. 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	None

II.B Summary of important risks

The safety information in the Product Information is aligned to the reference medicinal product.

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 Phenichem 18, 27, 36, 45 and 54 mg depottablett.

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

There are no studies required for Phenichem 18, 27, 36, 45 and 54 mg depottablett.