13 Part VI: Summary of the risk management plan for Methylphenidate hydrochloride, All oral formulations

This is a summary of the risk management plan (RMP) for methylphenidate hydrochloride, all oral formulations. The RMP details important risks of methylphenidate hydrochloride oral formulations, how these risks can be minimized, and how more information will be obtained methylphenidate hydrochloride oral formulations' risks and uncertainties (missing information).

Methylphenidate hydrochloride oral formulations' summaries of product characteristics (SmPCs) and its package leaflets give essential information to healthcare professionals and patients on how methylphenidate hydrochloride oral formulations should be used.

Important new concerns or changes to the current ones will be included in updates of the methylphenidate hydrochloride oral formulations' RMP.

13.1 Part VI: I. The medicine and what it is used for

Methylphenidate, oral formulations are authorized for:

Methylphenidate hydrochloride is indicated as part of a comprehensive treatment program for Attention Deficit Hyperactivity Disorder (ADHD) in children aged 6 years of age and over when remedial measures alone prove insufficient. Treatment must be under the supervision of a specialist in childhood behavioral disorders.

Methylphenidate hydrochloride treatment is not indicated in all children with ADHD and the decision to use the medicinal product must be based on a very thorough assessment of the severity and chronicity of the child's symptoms in relation to the child's age.

It contains methylphenidate hydrochloride as an active substance and is given orally as 10 mg tablets or 18 mg, 27 mg, 36 mg and 54 mg, prolonged release tablets.

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of methylphenidate hydrochloride oral formulations, together with measures to minimize such risks and the proposed studies for learning more about methylphenidate hydrochloride oral formulations' risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflets and SmPCs addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report (PSUR) assessment (if applicable) 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 methylphenidate hydrochloride oral formulations is not yet available, it is listed under 'missing information' below.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of methylphenidate hydrochloride oral formulations are risks that need special risk management activities to further investigate or minimize 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 methylphenidate hydrochloride oral formulations. 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	Serious cardiovascular events
	Psychosis/mania
	Verbal or motoric tics
	Depression
	Aggression
	Drug abuse/drug dependence
	Withdrawal syndrome
	Reduced weight gain
	Decreased rate of growth*
	Seizures
	Cerebrovascular disorders
	Neonatal toxicity**
Important potential risks	Sexual maturation delayed*
	Suicidality
Missing information	Long-term effects

* Only relevant for products with pediatric indications

** Only relevant for products with adult indications

13.2.2 Part VI – II.B: Summary of important risks

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

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of methylphenidate hydrochloride oral formulations.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for methylphenidate hydrochloride oral formulations.