Part VI: Summary of the risk management plan for Methylphenidate Orifarm

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

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

Important new concerns or changes to the current ones will be included in updates of Methylphenidate Orifarm's RMP.

I. The medicine and what it is used for

Methylphenidate Orifarm is intended for use in children and adolescents between the ages of 6 and 18, and in adults. It contains methylphenidate as the active substance and it is given by mouth. It is used only after treatments which do not involve medicine, such as counselling and behavioural therapy, and which have been insufficient.

Methylphenidate Orifarm improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention span and concentration, and reduce impulsive behaviour.

The medicine is given as part of a treatment programme, which usually includes:

- psychological
- educational and
- social therapy.

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

Important risks of Methylphenidate Orifarm, together with measures to minimise such risks and the proposed studies for learning more about Methylphendiate Orifarm´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 addition, checklists is available to the prescribing doctor to provide him/her with a readily accessible listing of what to check for prior to prescribing Methylphenidate Orifarm and during ongoing treatment.

If important information that may affect the safe use of Methylphenidate Orifarm is not yet available, it is listed under 'missing information' below.

In the case of Methylphenidate Orifarm, 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 Methylphenidate Orifarm is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Methylphenidate Orifarm 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 Methylphenidate Orifarm. 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);

Summary of safety concerns	
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	• Suicidality • Sexual maturation delayed
Missing information	• Long-term effects

II.B Summary of important risks

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

Important identified risk - Serious cardiovascular events	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8* *PL section 2* Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing* *Checklist 2: methylphenidate checklist for monitoring of ongoing therapy* *Chart for ongoing monitoring during methylphenidate treatment*

Important identified risk - Psychosis / Mania	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8* *PL section 2* Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing* *Checklist 2: methylphenidate checklist for monitoring of ongoing therapy*

Important identified risk - Verbal or motoric tics	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8* *PL section 2* Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing* *Checklist 2: methylphenidate checklist for monitoring of ongoing therapy*

Important identified risk - Depression	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8*

Important identified risk - Depression	
	PL section 2 Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing* *Checklist 2: methylphenidate checklist for monitoring of ongoing therapy*

Important identified risk - Aggression	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8* *PL section 2* Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing* *Checklist 2: methylphenidate checklist for monitoring of ongoing therapy*

Important identified risk - Drug abuse / Drug dependence	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8* *PL section 2* Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing* *Checklist 2: methylphenidate checklist for monitoring of ongoing therapy*

Important identified risk – Withdrawal symptoms	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8* *PL section 2* Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing* *Checklist 2: methylphenidate checklist for monitoring of ongoing therapy*

Important identified risk – Reduced weight gain	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8* *PL section 2* Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing* *Checklist 2: methylphenidate checklist for monitoring of ongoing therapy* *Chart for ongoing monitoring during methylphenidate treatment*

Important identified risk – Decreased rate of growth	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8* *PL section 2* Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing* *Checklist 2: methylphenidate checklist for monitoring of ongoing therapy* *Chart for ongoing monitoring during methylphenidate treatment*

Important identified risk - Seizures	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8* *PL section 2* Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing*

Important identified risk – Cerebrovascular disorders	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8* *PL section 2* Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing* *Checklist 2: methylphenidate checklist for monitoring of ongoing*

Important identified risk – Cerebrovascular disorders	
	therapy

Important identified risk – Neonatal toxicity	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8* *PL section 2* Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing* *Checklist 2: methylphenidate checklist for monitoring of ongoing therapy*

Important potential risk - Suicidality	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.3, 4.4 and 4.8* *PL section 2* Additional risk minimisation measures: *Physician's guide to prescribing* *Checklist 1: methylphenidate checklist before prescribing* *Checklist 2: methylphenidate checklist for monitoring of ongoing therapy* *Chart for ongoing monitoring during methylphenidate treatment*

Important potential risk – Sexual maturation delayed	
Risk minimisation measures	-

Missing information – long-term effects	
Risk minimisation measures	Routine risk minimisation measures: Routine risk minimisation measures: *SmPC section 4.2, 4.4, 5* *PL section* Additional risk minimisation measures: *None*

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 Methylphenidate Orifarm.

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

There are no studies required for Methylphenidate Orifarm.