Summary of the risk management plan

This is a summary of risk management plan (RMP) for Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets.

The RMP details important risks of Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets, how these risks can be minimised, and how more information will be obtained about Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets risks and uncertainties (missing information).

Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets RMP.

I. The medicine and what it is used for

Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets 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 Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets 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 Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets, these measures are supplemented with additional risk minimization measures for the 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.

If important information that may affect the safe use of Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets 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 Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets. 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 cardiovascular events
	Psychosis/mania
	Verbal or motoric tics
	Depression
	Aggression
	Drug abuse/Drug dependence

List of important risks and missing information

	Withdrawal syndrome
	Reduced weight gain
	Decreased rate of growth
	Seizures
	Cerebrovascular disorders
Important Potential Risks	Suicidality
	Sexual maturation delayed
Missing Information	Long-term effects

II.B Summary of important risks

Safety concern	**Risk minimisation measures**
Important Identified Risk: Serious cardiovascular events	Routine risk minimisation measures: SmPC: sections 4.2, 4.3, 4.4, 4.8. PL: sections 2 and 4. Additional risk minimisation measures: Introductory letter 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	Routine risk minimisation measures: SmPC: sections 4.2, 4.3, 4.4, 4.8. PL: sections 2 and 4. PL section 2. Additional risk minimisation measures: Introductory letter Checklist 1: methylphenidate checklist before prescribing Checklist 2: methylphenidate checklist for monitoring of ongoing therapy
Important Identified Risk: Verbal or motoric tics	Routine risk minimisation measures: SmPC: sections 4.4, 4.8. PL: section 2 and 4. Additional risk minimisation measures: Introductory letter Checklist 1: methylphenidate checklist before prescribing Checklist 2: methylphenidate checklist for monitoring of ongoing therapy
Important Identified Risk: Depression	Routine risk minimisation measures: SmPC: sections 4.3, 4.4, 4.8. PL: sections 2 and 4. Additional risk minimisation measures: Introductory letter Checklist 1: methylphenidate checklist before prescribing

	Checklist 2: methylphenidate checklist for monitoring of ongoing therapy
Important Identified Risk: Aggression	Routine risk minimisation measures: SmPC: sections 4.4, 4.8. PL: sections 2 and 4. Additional risk minimisation measures: Introductory letter Checklist 1: methylphenidate checklist before prescribing Checklist 2: methylphenidate checklist for monitoring of ongoing therapy
Important Identified Risk: Drug abuse/Drug dependence	Routine risk minimisation measures: SmPC: sections 4.1, 4.2, 4.4. PL: sections 1, 2 and 3. Additional risk minimisation measures: Introductory letter Checklist 1: methylphenidate checklist before prescribing Checklist 2: methylphenidate checklist for monitoring of ongoing therapy
Important Identified Risk: Withdrawal syndrome	Routine risk minimisation measures: SmPC: sections 4.4. PL: section 2. Additional risk minimisation measures: Introductory letter Checklist 1: methylphenidate checklist before prescribing Checklist 2: methylphenidate checklist for monitoring of ongoing therapy

Important Identified Risk: Reduced weight gain	Routine risk minimisation measures: SmPC: sections 4.2, 4.3, 4.4, 4.8. PL: sections 2 and 4. Additional risk minimisation measures: Introductory letter 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	Routine risk minimisation measures: SmPC: sections 4.2, 4.4, 4.8. PL: sections 3 and 4. Additional risk minimisation measures: Introductory letter 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	Routine risk minimisation measures: SmPC: sections 4.4, 4.8. PL: sections 2 and 4. Additional risk minimisation measures: Introductory letter Checklist 1: methylphenidate checklist before prescribing

Important Identified Risk: Cerebrovascular disorders	Routine risk minimisation measures: SmPC: sections 4.3, 4.4, 4.8. PL: sections 2 and 4. Additional risk minimisation measures: Introductory letter Checklist 1: methylphenidate checklist before prescribing Checklist 2: methylphenidate checklist for monitoring of ongoing therapy
Important Potential Risk: Suicidality	Routine risk minimisation measures: SmPC: sections 4.2, 4.3, 4.4, 4.8. PL: sections 2 and 4. Additional risk minimisation measures: Introductory letter Checklist 1: methylphenidate checklist before prescribing Checklist 2: methylphenidate checklist for monitoring of ongoing therapy

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 STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets.

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

There are no studies required for Methylphenidate STADA 18 mg, 27 mg, 36 mg and 54 mg prolonged-release tablets.