Part VI: Summary of the Risk Management Plan

As the safety concerns and their management are identical for all products covered by this RMP, the information in Part VI is presented only once together for all products.

Summary of risk management plan for Methylphenidat Zentiva (Methylphenidate)
This is a summary of the risk management plan (RMP) for Methylphenidat Zentiva. The RMP details important risks of Methylphenidat Zentiva, how these risks can be minimised, and how more information will be obtained about Methylphenidat Zentiva's risks and uncertainties (missing information).
Methylphenidat Zentiva's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Methylphenidat Zentiva should be used.

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

I. The medicine and what it is used for

Methylphenidat Zentiva is indicated as part of a comprehensive treatment programme for attentiondeficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over and adults when remedial measures alone prove insufficient. (see SmPC for the full indication). It contains Methylphenidate as the active substance and it is given by oral route of administration.

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

Important risks of Methylphenidat Zentiva, together with measures to minimise such risks and the proposed studies for learning more about Methylphenidat Zentiva'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 the case of Methylphenidat Zentiva, 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 Methylphenidat Zentiva is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Methylphenidat Zentiva 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 Methylphenidat Zentiva. 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 • 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

Summary of important risk that have corresponding additional risk minimisation activities are:

Important identified risk - Serious cardiovascular events	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC section 4.3, 4.4 and 4.8 PL section 2 and 4 Prescription only medicine <u>Additional risk minimisation measures:</u> - 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
Additional pharmacovigilance activities	<u>Additional pharmacovigilance activities:</u> Periodic literature screening of ADDUCE publications
Important identified risk - Psychosis/Mania	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC section 4.3, 4.4 and 4.8 PL section 2 and 4 Prescription only medicine

	<u>Additional risk minimisation measures:</u> - 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	<u>Routine risk minimisation measures:</u> SmPC section 4.4 and 4.8 PL section 2 and 4 Prescription only medicine <u>Additional risk minimisation measures:</u> - 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	<u>Routine risk minimisation measures:</u> SmPC section 4.3, 4.4 and 4.8 PL section 2 and 4 Prescription only medicine <u>Additional risk minimisation measures:</u> - 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	<u>Routine risk minimisation measures:</u> SmPC section 4.3, 4.4 and 4.8 PL section 2 and 4 Prescription only medicine <u>Additional risk minimisation measures:</u> - 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	<u>Routine risk minimisation measures:</u> SmPC section 4.4 and 4.8 PL section 2 and 4 Prescription only medicine <u>Additional risk minimisation measures:</u> - 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	<u>Routine risk minimisation measures:</u> SmPC section 4.4 and 4.8 PL section 2 and 4 Prescription only medicine <u>Additional risk minimisation measures:</u> - 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	<u>Routine risk minimisation measures:</u> SmPC section 4.3, 4.4 and 4.8 PL section 2 and 4 Prescription only medicine <u>Additional risk minimisation measures:</u> - 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

Additional pharmacovigilance activities	<u>Additional pharmacovigilance activities:</u> Periodic literature screening of ADDUCE publications
Important identified risk – Decreased rate of growth	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC section 4.4 and 4.8 PL section 2 and 4 Prescription only medicine <u>Additional risk minimisation measures:</u> - 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
Additional pharmacovigilance activities	<u>Additional pharmacovigilance activities:</u> Periodic literature screening of ADDUCE publications
Important identified risk - Seizures	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC section 4.4 and 4.8 PL section 2 and 4 Prescription only medicine <u>Additional risk minimisation measures:</u> - Physician's guide to prescribing - Checklist 1: methylphenidate checklist before prescribing
Important identified risk – Cerebrovascular disorders	

Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC section 4.3, 4.4 and 4.8 PL section 2 and 4 Prescription only medicine <u>Additional risk minimisation measures:</u> - Physician's guide to prescribing - Checklist 1: methylphenidate checklist before prescribing - Checklist 2: methylphenidate checklist for monitoring of ongoing therapy
Important identified risk – Neonatal toxicity	

Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.6 and 4.8 PL section 2 and 4 Prescription only medicine 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 and 4 Prescription only medicine 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 – Sexual maturation delayed	
Risk minimisation measures	-
Additional pharmacovigilance activities	Additional pharmacovigilance activities: Periodic literature screening of ADDUCE publications
Missing information – long-term effects	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.2, 4.4 and 5 PL section 3 Prescription only medicine Additional risk minimisation measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: Periodic literature screening of ADDUCE publications

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 Methylphenidat Zentiva.

II.C.2 Other studies in post-authorisation development plan There are no studies required for Methylphenidat Zentiva.