Summary of the risk management plan for Dexfarm

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

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

I. The medicine and what it is used for

Dexfarm is authorised as part of a comprehensive treatment program for attention- deficit/hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years when response to previous methylphenidate treatment is considered clinically inadequate. (see SmPC for the full indication).

It contains dexamfetamine sulfate as the active substance and it is given orally as tablets.

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

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

II.A List of important risks and missing information

Important risks of Dexfarm 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 Dexfarm. 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	• Myocardial infarction, sudden death, serious ischaemic cardiac or cardiovascular disorder, cardiomyopathy • Stroke, TIA and other cerebrovascular accidents • Psychiatric disorders (including psychotic symptoms, suicidality, aggression and hostility, depression, anorexia nervosa/anorectic disorders) • Tic/Tourette's/dystonia • Decreased rate of growth and development • Drug abuse, misuse and diversion • Dependence
	• Withdrawal syndrome
Important potential risks	• Off label use
Missing information	• Long-term safety (cardiovascular, neurological, cognition and psychotic)

II.B Summary of important risks

Safety Concern	***Routine risk minimisation activities***	***Pharmacovigilance activities***
Important identified risks		

Myocardial infarction, sudden death, serious ischaemic cardiac or cardiovascular disorder, cardiomyopathy	Routine risk communication: • SmPC: section 4.3, section 4.4, section 4.5, section 4.8 • PIL: section 2, section 3, section 4 Restricted medical prescription **Additional risk minimisations measures**	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: *None*. Additional pharmacovigilance activities: *None*.
Stroke, TIA and other cerebrovascular accidents	Routine risk communication: • *SmPC*: section 4.3, section 4.4, , section 4.8 • *PIL*: section 2, section 3, section 4 Restricted medical prescription Additional risk minimisations measures	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: *None*. Additional pharmacovigilance activities: *None*.
Psychiatric disorders (including psychotic symptoms, suicidality, aggression and hostility, depression, anorexia nervosa/anorectic disorders)	Routine risk communication: • *SmPC*: section 4.3, section 4.4, section 4.5, section 4.8 • *PIL*: section 2, section 3, section 4 Restricted medical prescription Additional risk minimisations measures	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: *None*. Additional pharmacovigilance activities: *None*.
Tic/Tourette's/dystonia	Routine risk communication: • SmPC: section 4.3, section 4.4, section 4.8 • PIL: section 2, section 3, section 4 Restricted medical prescription Additional risk minimisations measures	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: *None*. Additional pharmacovigilance activities: *None*.

Decreased rate of growth and development		
Drug abuse, misuse and diversion	Routine risk communication: • SmPC: section 4.1, section 4.3, section 4.4, section 4.8 • PIL: section 2, section 3, section 4 Restricted medical prescription Additional risk minimisations measures	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: *None*. Additional pharmacovigilance activities: *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 Dexfarm.

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

There are no studies required for Dexfarm.