

Summary of risk management plan for Methylphenidate Orion (methylphenidate hydrochloride) Orion Corporation

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

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

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

I. The medicine and what it is used for

Methylphenidate Orion is authorised for treatment of attention-deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when remedial measures alone prove insufficient (see SmPC for the full indication). It contains methylphenidate hydrochloride as the active substance and it is given by mouth.

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

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

II.A List of important risks and missing information

Important risks of Methylphenidate Orion 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 Orion. 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	<ul style="list-style-type: none"> • 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
Important potential risks	<ul style="list-style-type: none"> • Suicidality • Sexual maturation delayed
Missing information	<ul style="list-style-type: none"> • 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:

Important identified risk: Serious cardiovascular events

Information in SmPC sections 4.2, 4.3, 4.4, 4.5, 4.6, 4.8 and 4.9, and PL sections 2, 3 and 4.

Additional risk minimisation measures:

Educational material for healthcare professionals

Important identified risk: Psychosis/mania

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC sections 4.2, 4.3, 4.4 and 4.8, and PL sections 2, 3 and 4.

Additional risk minimisation measures:

Educational material for healthcare professionals

Important identified risk: Verbal or motoric tics

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC sections 4.2, 4.4 and 4.8, and PL sections 2, 3 and 4.

Additional risk minimisation measures:

Educational material for healthcare professionals

Important identified risk: Depression

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC sections 4.2, 4.3, 4.4 and 4.8, and PL section 2, 3 and 4.

Additional risk minimisation measures:

Educational material for healthcare professionals

Important identified risk: Aggression

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC sections 4.2, 4.4 and 4.8, and PL sections 2, 3 and 4.

Additional risk minimisation measures:

Important identified risk: Aggression

Educational material for healthcare professionals

Important identified risk: Drug abuse/Drug dependence

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC sections 4.2, 4.4 and 4.8, and PL sections 2 and 3.

Additional risk minimisation measures:

Educational material for healthcare professionals

Important identified risk: Withdrawal syndrome

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC section 4.4, and PL section 3 .

Additional risk minimisation measures:

Educational material for healthcare professionals

Important identified risk: Reduced weight gain

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC sections 4.2, 4.4 and 4.8, and PL sections 3 and 4.

Additional risk minimisation measures:

Educational material for healthcare professionals

Important identified risk: Decreased rate of growth

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC sections 4.2, 4.4 and 4.8, and PL sections 3 and 4.

Additional risk minimisation measures:

Educational material for healthcare professionals

Important identified risk: Seizures

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC sections 4.4 and 4.8, and PL sections 2 and 4.

Additional risk minimisation measures:

Educational material for healthcare professionals

Important identified risk: Cerebrovascular disorders

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC sections 4.3, 4.4, 4.5 and 4.8, and PL sections 2, 3 and 4.

Additional risk minimisation measures:

Educational material for healthcare professionals

Important potential risk: Suicidality

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC sections 4.2, 4.3, 4.4 and 4.8, and PL sections 2, 3 and 4.

Additional risk minimisation measures:

None

Important potential risk: Sexual maturation delayed

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC sections 4.2, 4.4 and 4.8, and PL sections 3 and 4.

Additional risk minimisation measures:

None

Missing information: Long-term effects

Risk minimisation measures

Routine risk minimisation measures:

Information in SmPC sections 4.2 and 4.4.

Missing information: Long-term effects	
	Additional risk minimisation measures: None

II.C Post-authorisation development plan

There are no studies required for Methylphenidate Orion.