

## Part VI: Summary of the risk management plan

# Summary of risk management plan for Methylphenidate Consilient Health 2 mg/ml oral solution(methylphenidate hydrochloride)

This is a summary of the risk management plan (RMP) for Methylphenidate Consilient Health 2 mg/ml oral solution(methylphenidate hydrochloride). The RMP details important risks of Methylphenidate Consilient Health 2 mg/ml oral solution, how these risks can be minimised, and how more information will be obtained about Methylphenidate Consilient Health 2 mg/ml oral solution's e risks and uncertainties (missing information).

Methylphenidate Consilient Health 2 mg/ml oral solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Methylphenidate Consilient Health 2 mg/ml oral solution should be used.

Important new concerns or changes to the current ones will be included in updates of Methylphenidate Consilient Health 2 mg/ml oral solution's 's eRMP.

## I. The medicine and what it is used for

Methylphenidate Consilient Health 2 mg/ml oral solution (methylphenidate hydrochloride) is indicated as a part of a comprehensive treatment programme for attention-deficit hyperactivity disorder (ADHD) in children and adolescents from the age of 6 years and older when other therapeutic measures alone have proved insufficient. Consilient Health 2 mg/ml oral solution (methylphenidate hydrochloride) is a secondline treatment for the relief of excessive daytime sleepiness in adult patients suffering from narcolepsy.

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

Important risks of methylphenidate, together with measures to minimise such risks and the proposed studies for learning more about Methylphenidate Consilient Health 2 mg/ml oral solution'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 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 is not yet available, it is listed under 'missing information' below.

### II.A List of important risks and missing information

Important risks of Methylphenidate Consilient Health 2 mg/ml oral solution 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 Consilient Health 2 mg/ml oral solution. 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);

<b>List of important risks and missing information</b>	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

### ***II.B Summary of important risks***

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

### ***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 Consilient Health 2 mg/ml oral solution..

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

There are no studies required for Methylphenidate Consilient Health 2 mg/ml oral solution..