Part VI: Summary of the risk management plan – Methylphenidat-HCL Humantis

Summary of risk management plan for Methylphenidat-HCL Humantis 5 mg / 10 mg / 20 mg / 30 mg / 40 mg / 50 mg / 60 mg modified-release capsules, hard (methylphenidate)

This is a summary of the risk management plan (RMP) for Methylphenidat-HCL Humantis 5 mg / 10 mg / 20 mg / 30 mg / 40 mg / 50 mg / 60 mg modified-release capsules, hard (hereinafter referred to as Methylphenidate Humantis). The RMP details important risks of Methylphenidate Humantis, how these risks can be minimised, and how more information will be obtained about Methylphenidate Humantis's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Methylphenidat-HCL Humantis is indicated as part of a comprehensive treatment programme for attention-deficit/hyperactivity disorder (ADHD) in children aged 6 years 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 (modified-release capsules, hard).

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

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

II.A List of important risks and missing information

Important risks of Methylphenidat-HCL Humantis 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-HCL Humantis. 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	• Serious Cardiovascular Events • Psychosis / Mania • Verbal or motoric tics • Depression • Aggression • Reduced Weight Gain* • Decreased Rate of Growth*
Important potential risks	• Suicidality • Sexual Maturation Delayed*
Missing information	• Long-Term Effects

*Risks applicable specifically to the paediatric population

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 Methylphenidat-HCL Humantis.

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

There are no studies required for Methylphenidat-HCL Humantis.