Part VI: Summary of the risk management plan

Summary of risk management plan for Methadone hydrochloride G.L. tablets (methadone hydrochloride)

This is a summary of the risk management plan (RMP) for Methadone hydrochloride G.L. tablets. The RMP details important risks of Methadone hydrochloride G.L. tablets and how more information will be obtained about Methadone hydrochloride G.L. tablets' risks and uncertainties (missing information).

Methadone hydrochloride G.L. tablets ' summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Methadone hydrochloride G.L. tablets should be used.

I. The medicine and what it is used for

Methadone hydrochloride G.L. tablets are authorised for maintenance treatment of opioid-dependent patients in parallel with medical and psychological treatment and social rehabilitation and treatment of severe chronic pain, which can be adequately managed only with opioid analgesics.

It contains methadone hydrochloride as the active substance and is given orally. Methadone hydrochloride G.L. tablets are available in strengths of 5 mg, 10 mg, 20 mg, 40 mg and 60 mg.

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

Important risks of Methadone hydrochloride G.L. tablets, together with measures to minimise such risks and the proposed studies for learning more about Methadone hydrochloride G.L. tablets' 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*.

II.A List of important risks and missing information

Important risks of Methadone hydrochloride G.L. tablets 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 Methadone hydrochloride G.L. tablets. 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	• Cardiac disease • Respiratory depression • Use in patients with hepatic impairment • Use in patients with renal impairment • Interactions with other drugs
Important potential risks	Use in pregnancy and lactation
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 Methadone hydrochloride G.L. tablets.

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

There are no studies required for Methadone hydrochloride G.L. tablets.