

Part VI: Summary of the risk management plan

Summary of risk management plan for Metformin hydrochloride film-coated tablets

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

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

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

I. The medicine and what it is used for

Metformin hydrochloride is authorised for treatment in patients with type 2 diabetes (also called 'non-insulin dependent diabetes') when diet and exercise alone have not been enough to control blood glucose levels. It is used particularly in overweight patients (see SmPC for the full indication). It contains metformin hydrochloride as the active substance and it is given by mouth as film-coated tablets. Metformin hydrochloride film-coated tablets are available in strengths of 500 mg 850 mg and 1000 mg.

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

Important risks of Metformin hydrochloride, together with measures to minimise such risks and the proposed studies for learning more about Metformin hydrochloride '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.

If important information that may affect the safe use of metformin hydrochloride is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Metformin hydrochloride 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 Metformin hydrochloride. 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"> Lactic acidosis (occurring with or without renal failure/impairment and/or concomitant use with iodinated contrast media)
Important potential risks	<ul style="list-style-type: none"> None
Missing information	<ul style="list-style-type: none"> Use in pregnancy and lactation

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 Metformin hydrochloride.

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

There are no studies required for Metformin hydrochloride.