Part VI: Summary of the risk management plan

Summary of risk management plan for Metforit (Metformin hydrochloride)

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

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

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

I. The medicine and what it is used for

Metforit is authorised for

Treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control.

- In adults, Metformin may be used as monotherapy or in combination with other oral antidiabetic agents or with insulin.
- In children from 10 years of age and adolescents, Metformin may be used as monotherapy or in combination with insulin.

A reduction of diabetic complications has been shown in overweight type 2 diabetic adult patients treated with metformin as first-line therapy after diet failure.

It contains metformin hydrochloride as the active substance and it is given by oral route in the form of film-coated tablets.

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

Important risks of Metforit, together with measures to minimise such risks and the proposed studies for learning more about Metforit'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 analyzed, including the targeted follow up questionnaire according to EMEA/H/A-31/1432, 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 Metforit is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Metforit 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 Metforit. 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	• Lactic acidosis with or without renal failure • Use in patients with renal dysfunction with GFR>30 ml/min • Concomitant use of iodinated contrast media
Important potential risks	• Leukocytoclastic vasculitis • Off-label use especially in female patients with PCOS
Missing information	• Use in children younger than 10 years • 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 Metforit.

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

There are no studies required for Metforit.