Part VI: Summary of the risk management plan by product

Summary of risk management plan for LYOMET.

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

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

I. The medicine and what it is used for

LYOMET are authorised for treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control.

Treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. LYOMET may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin (see SmPC for the full indication). It contains metformin hydrochloride as the active substance and it is given by oral administration.

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

Important risks of LYOMET, together with measures to minimise such risks and the proposed studies for learning more about LYOMET risks, are outlined below.

Measures to minimise the risks identified for medicinal product are:

- 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. Further, a targeted questionnaire is implemented in order to request and obtain from the reporter all relevant follow-up information including medical data available. These measures constitute *routine pharmacovigilance activities*.

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

II. A List of important risks and missing information

Important risks of LYOMET 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 LYOMET. 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 (occurring with or without renal failure and/or concomitant use with iodinated contrast media)
Important potential risks	• Leukocytoclastic vasculitis
Missing information	• Use during pregnancy and lactation

II.B Summary of important risks

The safety information in the 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 LYOMET.

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

There are no studies required for LYOMET.