

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Metformin/Sitagliptin Mylan (metformin/sitagliptin)

This is a summary of the risk management plan (RMP) for Metformin/Sitagliptin Mylan. The RMP details important risks of metformin/sitagliptin, how these risks can be minimised, and how more information will be obtained about metformin/sitagliptin's risks and uncertainties (missing information).

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

This summary of the RMP for Metformin/Sitagliptin Mylan should be read in the context of all the information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Metformin/Sitagliptin Mylan is authorised as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of sitagliptin and metformin or metformin and a sulfonylurea or metformin and a PPAR_γ agonist or insulin and metformin. It contains metformin/sitagliptin as the active substance and is given by oral route of administration as 850 mg/50 mg film-coated tablets or 1000 mg/50 mg film-coated tablets.

Further information about the evaluation of Metformin/Sitagliptin Mylan's benefits can be found in Metformin/Sitagliptin Mylan's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: <https://www.ema.europa.eu/en/medicines/human/EPAR/sitagliptin-metformin-mylan>.

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

Important risks of Metformin/Sitagliptin Mylan, together with measures to minimise such 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 public (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 events 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 Metformin/Sitagliptin Mylan is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Metformin/Sitagliptin Mylan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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/Sitagliptin Mylan. 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/use in special patient populations etc.);

Part VI: Summary of safety concerns

List of important risks and missing information	
Important identified risks	<ul style="list-style-type: none">• Lactic acidosis
Important potential risks	<ul style="list-style-type: none">• Pancreatic cancer
Missing information	<ul style="list-style-type: none">• Use in pregnancy and during breast-feeding

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/Sitagliptin Mylan.

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

There are no studies required for Metformin/Sitagliptin Mylan.