

Summary of risk management plan for Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets. The RMP details important risks of Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets risks and uncertainties (missing information).

Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets' prescribing information (SmPC/ PIL) give essential information to healthcare professionals and patients on how Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets should be used.

This summary of the RMP for Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets should be read in the context of all this 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 Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets' RMP.

I. The medicine and what it is used for

Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets is indicated for adult patients with type 2 diabetes mellitus.

- 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.
- In combination with a sulphonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea.
- As triple combination therapy with a peroxisome proliferator-activated receptor gamma (PPAR γ) agonist (i.e., a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPAR γ agonist.

- As add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when stable dose of insulin and metformin alone do not provide adequate glycaemic control.

It contains sitagliptin and metformin as the active substances and it is given by oral route.

Further information about the evaluation of Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets' benefits can be found in Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets' EPAR, including 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-hydrochloride-accord>

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

Important risks of Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets, 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 analysed, including PSUR assessment and signal management activity, 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 Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated 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 Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated 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);

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">• Exposure during 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 authorization or specific obligation of Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets.

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

There are no studies required for Sitagliptin/Metformin Accord 50/850 mg, 50/1000 mg film-coated tablets.