

**Part VI: Summary of the risk management plan****Summary of risk management plan for Metformin Accord 500/850/1000 mg film-coated tablets (Metformin hydrochloride)**

This is a summary of the risk management plan (RMP) for Metformin Accord 500/850/1000 mg film-coated tablets. The RMP details important risks of Metformin Accord 500/850/1000 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Metformin Accord 500/850/1000 mg film-coated tablets' risks and uncertainties (missing information).

Metformin Accord 500/850/1000 mg film-coated tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Metformin Accord 500/850/1000 mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Metformin Accord 500/850/1000 mg film-coated tablets' RMP.

**I. The medicine and what it is used for**

Metformin Accord 500 mg, 850 mg and 1000 mg film-coated tablets are indicated for the 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 hydrochloride 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 hydrochloride 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.

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

Important risks of Metformin Accord 500/850/1000 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Metformin Accord 500/850/1000 mg film-coated tablets' 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 analysed including PSUR assessment (if applicable) and signal management activity, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

### II.A List of important risks and missing information

Important risks Metformin Accord 500/850/1000 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 Metformin Accord 500/850/1000 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).

The data and conclusions included in this report are confidential and proprietary information of Marketing Authorization Holder.

Important identified risks	<ul style="list-style-type: none"> <li>Lactic acidosis (occurring with or without renal failure/impairment and/or concomitant use with iodinated contrast media)</li> </ul>
Important potential risks	<ul style="list-style-type: none"> <li>None</li> </ul>
Missing Information	<ul style="list-style-type: none"> <li>None</li> </ul>

## 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 Metformin Accord 500/850/1000 mg film-coated tablets.

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

There are no studies required for Metformin Accord 500/850/1000 mg film-coated tablets as post-authorisation development plan.