Part VI: Summary of the risk management plan

Summary of risk management plan for Pioglitazone Accord 15 mg, 30 mg and 45 mg tablets (pioglitazone)

This is a summary of the risk management plan (RMP) for Pioglitazone Accord 15 mg, 30 mg and 45 mg tablets. The RMP details important risks of Pioglitazone Accord 15 mg, 30 mg and 45 mg tablets, how these risks can be minimised, and how more information will be obtained about Pioglitazone Accord 15 mg, 30 mg and 45 mg tablets' risks and uncertainties (missing information).

Pioglitazone Accord 15 mg, 30 mg and 45 mg tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pioglitazone Accord 15 mg, 30 mg and 45 mg tablets should be used.

This summary of the RMP for Pioglitazone Accord 15 mg, 30 mg and 45 mg 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 Pioglitazone Accord 15 mg, 30 mg and 45 mg tablets' RMP.

I. The medicine and what it is used for

Pioglitazone is indicated as second or third line treatment of type 2 diabetes mellitus as described below:

As monotherapy

- In adult patients (particularly overweight patients) inadequately controlled by diet and exercise for whom metformin is in appropriate because of contraindications or intolerance.

As dual oral therapy in combination with

- Metformin, in adult patients (particularly overweight patients) with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin.

- A sulphonylurea, only in adult patients who show intolerance to metformin or for whom metformin is contraindicated, with insufficient glycaemic control despite maximal tolerated dose of monotherapy with a sulphonylurea.

As triple oral therapy in combination with

- Metformin and a sulphonylurea, in adult patients (particularly overweight patients) with insufficient glycaemic control despite dual oral therapy.

Pioglitazone is also indicated for combination with insulin in type 2 diabetes mellitus adult patients with insufficient glycaemic control on insulin for whom metformin is inappropriate because of contraindications or intolerance.

After initiation of therapy with pioglitazone, patients should be reviewed after 3 to 6 months to assess adequacy of response to treatment (e.g. reduction in HbA1c). In patients who fail to show an adequate response, pioglitazone should be discontinued. In light of potential risks with prolonged therapy, prescribers should confirm at subsequent routine reviews that the benefit of pioglitazone is maintained.

It contains pioglitazone as the active substance and it is for oral use only.

Further information about the evaluation of Pioglitazone Accord 15 mg, 30 mg and 45 mg tablet's benefits can be found in Pioglitazone Accord 15 mg, 30 mg and 45 mg tablets 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/pioglitazone-accord.

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

Important risks of Pioglitazone Accord 15 mg, 30 mg and 45 mg tablets, together with measures to minimise such risks and the proposed studies for learning more about Pioglitazone Accord 15 mg, 30 mg and 45 mg 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 Pioglitazone Accord 15 mg, 30 mg and 45 mg 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 Pioglitazone Accord 15 mg, 30 mg and 45 mg 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).

II.B Summary of important risks

The safety information in the proposed product information is aligned to the reference medicinal product.

Important identified risks (s)	• None

Important potential risks	• None
Missing information	• None

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 Pioglitazone Accord 15 mg, 30 mg and 45 mg tablets.

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

There are no studies required for Pioglitazone Accord 15 mg, 30 mg and 45 mg tablets as post-authorisation development plan.