Summary of risk management plan for Actos (Pioglitazone)

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

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

This summary of the RMP for Actos 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 Actos's RMP.

I. The medicine and what it is used for

Actos is authorised for second- or third line treatment of type II diabetes mellitus as described below:

as **monotherapy**

- in adult patients (particularly overweight patients) inadequately controlled by diet and exercise for whom metformin is inappropriate 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 sulfonylurea, 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 sulfonylurea;

As **triple oral therapy** in combination with

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

Actos is also indicated for combination with insulin in type II diabetes mellitus adult patients with insufficient glycaemic control on insulin for whom metformin is inappropriate because of contraindications or intolerance (see SmPC for the full indication). It contains pioglitazone as the active substance and it is given by mouth as a tablet.

Further information about the evaluation of Actos's benefits can be found in Actos'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/actos

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

Important risks of Actos, together with measures to minimise such risks and the proposed studies for learning more about Actos's 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 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 Actos is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Actos 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 Actos. 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	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable.

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 Actos.

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

There are no studies required for Actos.