Part VI: Summary of the risk management plan

Summary of risk management plan for

Sitagliptin Grindeks 25 mg film-coated tablets
Sitagliptin Grindeks 50 mg film-coated tablets
Sitagliptin Grindeks 100 mg film-coated tablets

(sitagliptin)

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

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

I. The medicine and what it is used for

Sitagliptin Grindeks is authorised for adult patients with type 2 diabetes mellitus to improve glycaemic control. It contains sitagliptin as the active substance and it is given by oral route of administration in concentration of 25 mg, 50 mg or 100 mg per tablet.

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

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

II.A List of important risks and missing information

Important risks of Sitagliptin Grindeks are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Grindeks. 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).

Summary of safety concerns	
Important identified risks	*None*
Important potential risks	*Pancreatic cancer*
Missing information	*Exposure during pregnancy and lactation*

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medical 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 Sitagliptin Grindeks.

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

There are no studies required for Sitagliptin Grindeks.