Part VI: Summary of the risk management plan

Summary of risk management plan for Sitagliptin beta Filmtabletten (sitagliptin)

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

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

Important new concerns or changes to the current ones will be included in updates of Sitagliptin beta Filmtabletten's RMP.

I. The medicine and what it is used for

Sitagliptin beta Filmtabletten is authorised to improve glycaemic control in adult patients with type 2 diabetes mellitus (see SmPC for the full indications). It contains sitagliptin as the active substance and it is given orally.

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

Important risks of Sitagliptin beta Filmtabletten, together with measures to minimise such risks and the proposed studies for learning more about Sitagliptin beta mg Filmtabletten'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.

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 beta Filmtabletten is not yet available, it is listed under 'missing information' below

II.A List of important risks and missing information

Important risks of Sitagliptin beta Filmtabletten 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 Filmtabletten. 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	• Hypersensitivity reactions, including anaphylactic reaction, angioedema, rash, urticaria, cutaneous vasculitis, skin exfoliation and Stevens-Johnson syndrome • Hypoglycaemia with concomitant sulphonylurea • Hypoglycaemia with concomitant insulin • Gastrointestinal disorders: nausea, vomiting, constipation, diarrhoea, abdominal pain, flatulence, abdominal pain upper and related terms (dyspepsia and gastritis) • Musculoskeletal disorders: osteoarthritis, pain in extremity, and related terms (e.g. arthralgia, myalgia, myopathy) • Pancreatitis
Important potential risks	• Infections: Upper respiratory tract infection, nasopharyngitis and related terms (bronchitis, acute bronchitis, pharyngitis, sinusitis, and rhinitis) • Neurotoxicity, including tremor, ataxia, and balance disorders • Suicidal ideation/ suicide, including depression • Skin reactions: contact dermatitis • Impaired renal function, including acute renal failure (sometimes requiring dialysis) • Pancreatic cancer • Rhabdomyolysis
Missing information	• Exposure in patients < 18 years of age • Exposure during pregnancy and lactation • Theoretic carcinogenic potential

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 authorisation or specific obligation of Sitagliptin beta Filmtabletten.

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

There are no studies required for Sitagliptin beta Filmtabletten.