

## **PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN**

### **Summary of risk management plan for Sitagliptin**

This is a summary of the risk management plan (RMP) for Sitagliptin Mylan and Exzensi 25 mg, 50 mg and 100 mg Film-coated tablets. The RMP details important risks of sitagliptin, and how more information will be obtained about sitagliptin 's risks and uncertainties (missing information). Sitagliptin Mylan and Exzensi 25 mg, 50 mg and 100 mg Film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

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

Sitagliptin Mylan and Exzensi 25 mg, 50 mg and 100 mg film-coated tablets is authorised for adult patients with type 2 diabetes mellitus, sitagliptin is indicated to improve glycaemic control:

As monotherapy

- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

As dual oral therapy in combination with

- metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control.
- a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance.
- a peroxisome proliferator-activated receptor gamma (PPAR $\gamma$ ) agonist (i.e. a thiazolidinedione) when use of a PPAR $\gamma$  agonist is appropriate and when diet and exercise plus the PPAR $\gamma$  agonist alone do not provide adequate glycaemic control.

As triple oral therapy in combination with

- a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.
- a PPAR $\gamma$  agonist and metformin when use of a PPAR $\gamma$  agonist is appropriate and when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.

## **Risk Management Plan Sitagliptin Version 1.1**

Sitagliptin Mylan and Exzensi 25 mg, 50 mg and 100 mg film-coated tablets is also indicated as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycaemic control. It contains sitagliptin as the active substance and it is given by oral administration

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

Important risks of Sitagliptin Mylan and Exzensi 25 mg, 50 mg and 100 mg Film-coated tablets, together with measures to minimise such 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 public (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 events 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 is not yet available, it is listed under 'missing information' below.

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

Important risks of Sitagliptin Mylan and Exzensi 25 mg, 50 mg and 100 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 administered to/taken by patients. 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 Mylan and Exzensi 25 mg, 50 mg and 100 mg Film-

## **Risk Management Plan Sitagliptin Version 1.1**

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/use in special patient populations etc.);

Table 4 Part VI: Summary of safety concerns

<b>List of important risks and missing information</b>	
Important identified risks	<ul style="list-style-type: none"><li>• None</li></ul>
Important potential risks	<ul style="list-style-type: none"><li>• Pancreatic cancer</li></ul>
Missing information	<ul style="list-style-type: none"><li>• Exposure during pregnancy and lactation.</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 authorisation or specific obligation of sitagliptin.

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

There are no studies required for sitagliptin.