

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for Vildagliptin/Metformin STADA 50 mg/850 mg and 50 mg/1000 mg film-coated tablets (Vildagliptin/Metformin)**

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

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

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

Vildagliptin/Metformin STADA is authorised for the treatment of type 2 diabetes mellitus in adult patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets; in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled with metformin and a sulphonylurea; in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in adult patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control (see SmPC for the full indication). It contains vildagliptin and metformin as the active substances and it is given orally.

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

Important risks of Vildagliptin/Metformin STADA, together with measures to minimise such risks and the proposed studies for learning more about Vildagliptin/Metformin STADA'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.

If important information that may affect the safe use of Vildagliptin/Metformin STADA is not yet available, it is listed under 'missing information' below.

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

Important risks of Vildagliptin/Metformin STADA 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 Vildagliptin/Metformin STADA. 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);

<b>Summary of safety concerns</b>	
Important identified risks	<ul style="list-style-type: none"> <li>• Transaminase elevation and drug-induced liver injury (DILI)</li> <li>• Angioedema</li> <li>• Acute pancreatitis</li> <li>• Lactic acidosis</li> <li>• Skin lesions</li> <li>• Hypoglycaemia</li> </ul>
Important potential risks	<ul style="list-style-type: none"> <li>• Serious infections</li> <li>• Cardiac events in congestive heart failure (<i>NYHA functional class III</i>) patients</li> <li>• Muscle events/myopathy/rhabdomyolysis, in particular with current statin use</li> <li>• Neuropsychiatric events</li> <li>• Breast cancer</li> <li>• Pancreatic cancer</li> </ul>
Missing information	<ul style="list-style-type: none"> <li>• Gender incidence/frequency differences</li> <li>• Patients with severe hepatic impairment</li> <li>• Patients with compromised cardiac function (<i>NYHA functional class IV</i>)</li> <li>• Pregnancy</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 Vildagliptin/Metformin STADA.

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

There are no studies required for Vildagliptin/Metformin STADA.