Part VI: Summary of the risk management plan

Summary of risk management plan for Vildagliptin STADA 50 mg tabletter (Vildagliptin)

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

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

I. The medicine and what it is used for

Vildagliptin STADA is authorised for the treatment of type 2 diabetes mellitus in adults 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 in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin; a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance, a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate); 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). Vildagliptin is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control (see SmPC for the full indication). It contains vildagliptin 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 Vildagliptin STADA, together with measures to minimise such risks and the proposed studies for learning more about Vildagliptin 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 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 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 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);

List of important risks and missing information	
Important identified risks	• Transaminase elevation and Drug-induced liver injury (DILI) • Angioedema • Acute pancreatitis • Skin lesions • Hypoglycaemia
Important potential risks	• Serious infections • Cardiac events in CHF (*NYHA Functional Class III*) patients • Muscle events/myopathy/rhabdomyolysis, in particular with current statin use • Neuropsychiatric events • Breast cancer • Pancreatic cancer
Missing information	• Gender incidence/frequency differences • Patients with severe hepatic impairment • Patients with compromised cardiac function (*NYHA functional class IV*) • Pregnancy

II.B Summary of important risks

Transaminase elevation and Drug-induced liver injury (DILI) **Important identified risk**	
Risk minimisation measures	Prescription only medicine <u>Routine risk minimisation measures:</u> • *SmPC sections 4.4 and 4.8* <u>Additional risk minimisation measures:</u> • *None*
	<u>Additional pharmacovigilance activities:</u> • None

Angioedema **Important identified risk**	
Risk minimisation measures	Prescription only medicine Routine risk minimisation measures: • *SmPC sections 4.5 and 4.8* Additional risk minimisation measures: • *None*
	Additional pharmacovigilance activities: • None

Acute pancreatitis **Important identified risk**	
Risk minimisation measures	Prescription only medicine Routine risk minimisation measures: • *SmPC sections 4.4 and 4.8* Additional risk minimisation measures: • *None*
	Additional pharmacovigilance activities: • None

Skin lesions **Important identified risk**	
Risk minimisation measures	Prescription only medicine Routine risk minimisation measures: • *SmPC sections 4.4 and 4.8* Additional risk minimisation measures: • *None*
	Additional pharmacovigilance activities: • None

Hypoglycaemia **Important identified risk**

Risk minimisation measures	Prescription only medicine Routine risk minimisation measures: • *SmPC sections 4.4 and 4.8* Additional risk minimisation measures: • *None*
	Additional pharmacovigilance activities: • None

Serious infections **Important potential risk**	
Risk minimisation measures	Prescription only medicine Routine risk minimisation measures: • *SmPC section 4.8* Additional risk minimisation measures: • *None*
	Additional pharmacovigilance activities: • None

Cardiac events in CHF (NYHA Functional Class III) patients **Important potential risk**	
Risk minimisation measures	Prescription only medicine Routine risk minimisation measures: • *SmPC sections 4.4 and 5.1* Additional risk minimisation measures: • *None*
	Additional pharmacovigilance activities: • None

Muscle events/myopathy/rhabdomyolysis, in particular with current statin use **Important potential risk**	
Risk minimisation measures	Prescription only medicine Routine risk minimisation measures:

	• *Currently available data do not support the need for risk minimisation measures* Additional risk minimisation measures: • *None*
	Additional pharmacovigilance activities: • None

Neuropsychiatric events **Important potential risk**	
Risk minimisation measures	Prescription only medicine Routine risk minimisation measures: • *SmPC section 4.8* Additional risk minimisation measures: • *None*
	Additional pharmacovigilance activities: • None

Breast cancer **Important potential risk**	
Risk minimisation measures	Prescription only medicine Routine risk minimisation measures: • *Currently available data do not support the need for risk minimisation measures* Additional risk minimisation measures: • *None*
	Additional pharmacovigilance activities: • None

Pancreatic cancer **Important potential risk**	
Risk minimisation measures	Prescription only medicine Routine risk minimisation measures:

	• *Currently available data do not support the need for risk minimisation measures* <u>Additional risk minimisation measures:</u> • *None*
	<u>Additional pharmacovigilance activities:</u> • None

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 STADA.

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

There are no studies required for Vildagliptin STADA.