Swiss Summary of the Risk Management Plan (RMP) for Vipidia® (alogliptin)

Version 1.0, 7-Feb-2023
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The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risk as well as to prevent or minimize them.

The RMP summary of Vipidia® is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Vipidia® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Takeda Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Vipidia®.

Summary of risk management plan for Vipidia® (alogliptin)

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

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

This summary of the RMP for VIPIDIA should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

VIPIDIA is authorised for adults aged 18 years and older with type 2 diabetes mellitus to improve glycemic control in combination with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. (see SmPC for the full indication). It contains alogliptin as the active substance and it is given orally as 6.25 mg, 12.5 mg or 25 mg film-coated tablets.

Further information about the evaluation VIPIDIA's benefits can be found in VIPIDIA's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:

https://www.ema.europa.eu/en/medicines/human/EPAR/vipidia

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

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment 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 VIPIDIA is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of VIPIDIA 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 VIPIDIA's. 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	None
Important potential risks	Pancreatic cancer Arthralgia
Missing information	Use in pregnant women and breast feeding

II.B Summary of important risks

Important Potential Risk: Pancreatic cancer	
Evidence for linking the risk to the medicine	Alogliptin clinical trials OPI-004,305, and 402 and post-marketing database, published literature.
Risk factors and risk groups	There are known risk factors associated with development of pancreatic cancer; among these are gender (men are 30% more at risk), age (70% are age 65 years or older), race (African-Americans are at higher risk), smoking (responsible for 20%-30% of pancreatic cancers), obesity, diabetes, chronic pancreatitis, liver cirrhosis, family history, occupational exposure to pesticides, dyes, chemicals used in metal refining, and genetic syndromes, such as mutations in genes such as BRCA2, p16/CDKN2A (familial melanoma), and PRSSi (familial pancreatitis), Lynch syndrome (also known as hereditary nonpolyposis colorectal cancer), Peutz-Jeghers syndrome, von Hippel-Lindau syndrome, neurofibromatosis type 1 (gene mutation), and multiple endocrine neoplasia type 1.
Risk minimization measures	**Routine risk minimisation measures:** None **Additional risk minimisation measures:** None
Additional pharmacovigilance activities	None

Important Potential Risk: Arthralgia	
Evidence for linking the risk to the medicine	Alogliptin clinical studies, post-marketing safety surveillance database, non-clinical data, and scientific literature.
Risk factors and risk groups	Elderly patients and women. The major cause of musculoskeletal pain is osteoarthritis. Additional causes for joint pain include injuries, mechanical problems, obesity and overweight, types of arthritis and other health problems.

Important Potential Risk: Arthralgia	
Risk minimization measures	**Routine risk minimisation measures:** None **Additional risk minimisation measures:** None
Additional pharmacovigilance activities	None

Missing Information: Use in pregnant women and breast feeding	
Risk minimization measures	**Routine risk minimisation measures:** SmPC Section 4.6 and PL Section 2 recommends to avoid the use of alogliptin during pregnancy and considerations related to lactation. **Additional risk minimisation measures:** 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 VIPIDIA.

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

There are no studies required for VIPIDIA.