PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

VYDURA (RIMEGEPANT)

Marketing Authorization Number 69035

Oral lyophylisate, 75 mg

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LIST OF ABBREVIATIONS

AE	Adverse Event
EMA	European Medicines Agency
EPAR	European Public Assessment Report
MACE	Major Adverse Cardiovascular Events
PASS	Post-Authorisation Safety Study
PL	Patient Leaflet
RMP	Risk Management Plan
SmPC	Summary Of Product Characteristics

OVERVIEW

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 risks as well as to prevent or minimise them. The RMP summary for Vydura 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 marketing authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Vydura in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorised by Swissmedic. Pfizer is fully responsible for the accuracy and correctness of the content of the published RMP summary of Vydura.

SUMMARY OF RISK MANAGEMENT PLAN FOR VYDURA

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

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

This summary of the RMP for Vydura 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 Vydura's RMP.

I. The Medicine and What It Is Used For

Vydura is authorised for the acute treatment of migraine and preventive treatment of episodic migraine in adults. It contains rimegepant as the active substance and it is given by oral route in orodispersible tablets (75 mg).

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

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Vydura, together with measures to minimise such risks and the proposed studies for learning more about Vydura'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 (eg, 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 periodic safety report assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A. List of Important Risks and Missing Information

Important risks of Vydura 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 Vydura. 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 (eg, on the long-term use of the medicine).

Table 1. List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing information	Use in pregnant women Use in patients with cardiovascular diseases

II.B. Summary of Important Risks

Table 2. Summary of important risks

Missing information – Use in pregnant women	
Risk minimisation measures	Routine risk communication: SmPC section 4.6 PL section 4 Legal status: prescription only medication. No additional risk minimisation measures
Additional pharmacovigilance activities	Additional pharmacovigilance activities: Rimegepant Pregnancy Registry study (BHV3000-402) Rimegepant Pregnancy Outcomes study (BHV3000-403) See section II.C of this summary for an overview of the post-authorisation development plan.
Missing information – Use in patients with cardiovascular diseases	
Risk minimisation measures	Legal status: prescription only medication No additional risk minimisation measures
Additional pharmacovigilance activities	A PASS will be conducted to characterize new rimegepant users in terms of their cardiovascular risk and to evaluate the incidence of MACE outcomes in this population. See section II.C of this summary for an overview of the post- authorization development plan.

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.

II.C.2 Other Studies in Post-Authorisation Development Plan

The following 2 studies characterizing the safety of rimegepant use in pregnant women are ongoing.

BHV3000-402: a prospective, registry-based, observational study to assess maternal, fetal, and infant outcomes following exposure to rimegepant.

Primary Endpoint: To compare the occurrence of major congenital malformations in the fetuses/infants of women with migraine exposed to rimegepant during pregnancy or just prior to pregnancy (up to 3 days prior to conception) to 1) an internal cohort of women with migraine not exposed to rimegepant before or during pregnancy and 2) an external cohort of pregnant women without migraine.

Secondary Endpoints:

To describe the occurrence of adverse fetal outcomes, maternal pregnancy complications, infant outcomes at birth, and infant events of interest up to 1 year post delivery in women with migraine exposed to rimegepant during pregnancy or just prior to pregnancy (up to 3 days prior to conception), and to form comparisons to the same outcomes in 1) an internal cohort of women with migraine not exposed to rimegepant before or during pregnancy and 2) an external cohort of pregnant women without migraine:

- Fetal outcomes
- Maternal pregnancy complications
- Infant outcomes
- Other AEs

BHV3000-403: a retrospective cohort study of pregnancy outcomes in women exposed to rimegepant during pregnancy

Primary Endpoint: To evaluate the risk of pregnancy and infant outcomes among women with migraine exposed to rimegepant during pregnancy and in 2 rimegepant-unexposed comparator groups.

Specific:

- To describe patterns of use of rimegepant in pregnant women
- To estimate the frequency of pregnancy outcomes and fetal/infant outcomes
- To estimate the adjusted relative risks for the study outcomes among women exposed to rimegepant in pregnancy compared with each of the 2 unexposed comparator groups

The following PASS study to characterize the risk in patients with cardiovascular diseases is proposed.

[Study number to be assigned]: Post-authorisation safety study of rimegepant in patients with migraine and a history of cardiovascular diseases.

Primary Endpoint: 1) to compare the incidence rate of major adverse cardiovascular events (MACE) in new users of rimegepant with migraine and a history of cardiovascular diseases with the incidence rate of MACE in migraine patients with a history of cardiovascular diseases who are on other migraine treatments; and 2) to describe the characteristics and patterns of use of rimegepant among new users with migraine and a history of cardiovascular diseases.