



RISK MANAGEMENT PLAN

For
Sildenafil citrate
Version 5.0

RMP Version to be Assessed as Part of this Application:

RMP Version Number	5.0
Data Lock Point for this RMP	23-Feb-2024
Date of Final Sign Off	10-Jul-2024
Rationale for Submitting an Updated RMP	The MAH is submitting the updated RMP for sildenafil in line with the innovator's updated RMP for Revatio. Submitting the updates in new template (EMA/164014/2018 Rev.2.0.1 accompanying GVP Module V Rev.2)
Summary of Significant Changes in this RMP	Proposal to remove "Long-term Mortality" as missing information.

Other RMP Versions Under Evaluation:

RMP Version Number	Not applicable
Submitted On	Not applicable
Procedure Number	Not applicable

Details of the Current RMP:

Version Number	4.1
Approved with Procedure	EMA/H/C/004186/IB/0011
Date of Approval (Opinion Date)	03-Jun-2022

Approver	Dr Eiko Soehlke, MD MPH, EEA QPPV
Signature	RMP has been reviewed and approved by the marketing authorisation applicant's QPPV and that the electronic signature is on file.
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LIST OF ABBREVIATIONS

Abbreviation	Definition
ADR	Adverse drug reaction
ATC	Anatomical Therapeutic Chemical Classification System
CHMP	Committee for Medicinal Products for Human Use
CMDh	Coordination Group for Mutual recognition and Decentralised Procedures – Human
DCP	Decentralised Procedure
DDD	Daily Defined Dose
DHPC	Direct Healthcare Professional Communication
EEA	European Economic Area
EPAR	European Public Assessment Report
EU	European Union
EURD	European Union Reference Date
HCP	Healthcare Professional
ICSR	Individual Case Safety Report
MAA	Marketing Authorization Applicant
MAH	Marketing Authorization Holder
MRP	Mutual Recognition Procedure
PAC	Patient Alert Card
PL	Package leaflet
PPP	Pregnancy Prevention Programme
PRAC	Pharmacovigilance Risk Assessment Committee
PSUR	Periodic Safety Update Report
PTC	Patient treatment course
PTD	Patient treatment Days
PTM	Patient treatment Months
PTY	Patient treatment Years
PVA	Pharmacovigilance Agreement
QPPV	Qualified Person for Pharmacovigilance
MedDRA	Medical Dictionary for Regulatory Activities
DLP	Data Lock Point
SPC	Summary of Product Characteristics
WHO	World Health Organization

PART I: PRODUCT(S) OVERVIEW

Table 1: Part 1.1-Product Overview

Active Substance(s) (INN or Common Name)	Sildenafil citrate
Pharmacotherapeutic Group(s) (ATC Code)	Urologicals, Drugs used in erectile dysfunction. ATC Code: G04B E03.
Marketing Authorisation Holder	Viatriis Limited
Medicinal Products to Which this RMP Refers	1
Invented Name(s) in the European Economic Area (EEA)	Mysildecard 20 mg film-coated tablets
Marketing Authorisation Procedure	EMA/H/C/004186
Brief Description of the Product	Sildenafil belongs to pharmacotherapeutic group: Urologicals, Drugs used in erectile dysfunction (ATC code: G04BE03). <u>Mechanism of action:</u> Sildenafil is a potent and selective inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5), the enzyme that is responsible for degradation of cGMP. Apart from the presence of this enzyme in the corpus cavernosum of the penis, PDE5 is also present in the pulmonary vasculature. Sildenafil, therefore, increases cGMP within pulmonary vascular smooth muscle cells resulting in relaxation. In patients with pulmonary arterial hypertension this can lead to vasodilation of the pulmonary vascular bed and, to a lesser degree, vasodilation in the systemic circulation. Each film-coated tablet contains 20 mg of sildenafil (as citrate).
Hyperlink to the Product Information:	PI available in Section 1.3.1 of the dossier
Indication(s) in the EEA	Mysildecard is indicated in Adults: Treatment of adult patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease. Paediatric population: Treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension who are able to swallow the tablets. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease.

Dosage in the EEA	Treatment should only be initiated and monitored by a physician experienced in the treatment of pulmonary arterial hypertension. In case of clinical deterioration in spite of Mysildecard treatment, alternative therapies should be considered. Posology <i>Adults:</i> The recommended dose is 20 mg three times a day. Physicians should advise patients who forget to take Mysildecard to take a dose as soon as possible and then continue with the normal dose. Patients should not take a double dose to compensate for the missed dose. <i>Paediatric population (1 year to 17 years):</i> For paediatric patients aged 1 year to 17 years old, the recommended dose in patients ≤ 20 kg is 10 mg three times a day and for patients > 20 kg is 20 mg three times a day. Higher than recommended doses should not be used in paediatric patients with PAH (see also sections 4.4 and 5.1). The 20 mg tablet should not be used in cases where 10 mg TID should be administered in younger patients. Other pharmaceutical forms are available for administration to patients ≤ 20 kg and other younger patients who are not able to swallow tablets. <i>Patients using other medicinal products:</i> In general, any dose adjustment should be administered only after a careful benefit-risk assessment. A downward dose adjustment to 20 mg twice daily should be considered when sildenafil is co-administered to patients already receiving CYP3A4 inhibitors like erythromycin or saquinavir. A downward dose adjustment to 20 mg once daily is recommended in case of co-administration with more potent CYP3A4 inhibitors clarithromycin, telithromycin and nefazodone. For the use of sildenafil with the most potent CYP3A4 inhibitors, further information in product information. Dose adjustments for sildenafil may be required when co-administered with CYP3A4 inducers. <i>Special populations</i> <i>Elderly (≥ 65 years):</i> Dose adjustments are not required in elderly patients. Clinical efficacy as measured by 6-minute walk distance could be less in elderly patients. <i>Renal impairment:</i> Initial dose adjustments are not required in patients with renal impairment, including severe renal impairment (creatinine clearance < 30 ml/min). A downward dose adjustment to 20 mg twice daily should be considered after a careful benefit-risk assessment only if therapy is not well-tolerated. <i>Hepatic impairment:</i> Initial dose adjustments are not required in patients with hepatic impairment (Child-Pugh class A and B). A downward dose adjustment to 20 mg twice daily should be considered after a careful benefit-risk assessment only if therapy is not well-tolerated. Sildenafil is contraindicated in patients with severe hepatic impairment (Child-Pugh class C). <i>Paediatric population(children less than 1 year and neonates):</i> Outside its authorised indications, sildenafil should not be used in neonates with persistent pulmonary hypertension of the newborn as risks outweigh the
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	benefits (see section 5.1). The safety and efficacy of sildenafil in other conditions in children below 1 year of age has not been established. No data are available. <i>Discontinuation of treatment</i> Limited data suggests that the abrupt discontinuation of sildenafil is not associated with rebound worsening of pulmonary arterial hypertension. However, to avoid the possible occurrence of sudden clinical deterioration during withdrawal, a gradual dose reduction should be considered. Intensified monitoring is recommended during the discontinuation period. Method of administration Mysildecard is for oral use only. Tablets should be taken approximately 6 to 8 hours apart with or without food.
Pharmaceutical Form(s) and Strengths	Mysildecard 20 mg film-coated tablets A white, film-coated, round, biconvex tablet debossed with M on one side of the tablet and SL over 20 on the other side.
Is/Will the Product Be Subject to Additional Monitoring in the EU?	No

PART II: SAFETY SPECIFICATION

Part II: Module SI - Epidemiology of the Indication(s) and Target Population(s)

Not applicable.

Part II: Module SII - Non-clinical Part of the Safety Specification

Not applicable.

Part II: Module SIII - Clinical Trial Exposure

Not applicable.

Part II: Module SIV - Populations Not Studied in Clinical Trials

SIV.1 Exclusion Criteria in Pivotal Clinical Studies Within the Development Programme

Not applicable.

SIV.2 Limitations to Detect Adverse Reactions in Clinical Trial Development Programmes

Not applicable.

SIV.3 Limitations in Respect to Populations Typically Under-represented in Clinical Trial Development Programmes

Part II: Module SV - Post-authorisation Experience

Not applicable.

Part II: Module SVI - Additional EU Requirements for the Safety Specification

Not applicable.

Part II: Module SVII - Identified and Potential Risks

SVII.1 Identification of Safety Concerns in the Initial RMP Submission

Viartis has an approved RMP Version 4.1, approved on 03-Jun-2022, for sildenafil procedure EMEA/H/C/004186, with the following safety concerns:

Table 2: SVII- Summary of safety concerns

Summary of Safety Concerns	
Important Identified Risks	- Vaso-occlusive crisis in patients with sickle cell disease - Increased relative mortality in the paediatric population

Summary of Safety Concerns	
	• Bleeding events (excluding epistaxis)
Important Potential Risks	• Non-arteritic anterior ischaemic optic neuropathy (NAION) • Pulmonary haemorrhage in paediatric patients
Missing Information	• Long-term ocular safety • Safety in pregnancy • Long-term mortality

SVII.1.1. Risks Not Considered Important for Inclusion in the List of Safety Concerns in the RMP

Not applicable.

SVII.1.2. Risks Considered Important for Inclusion in the List of Safety Concerns in the RMP

Not applicable.

SVII.2 New Safety Concerns and Reclassification with a Submission of an Updated RMP

The MAH has updated its RMP to remove “Long-term Mortality” as missing information to align with the innovator’s updated RMP for Revatio, Version 8.0, dated 30-Nov-2022.

SVII.3 Details of Important Identified Risks, Important Potential Risks, and Missing Information

SVII.3.1. Presentation of Important Identified Risks and Important Potential Risks

Not applicable as this RMP for sildenafil follows the same safety concerns of the approved Viatrix’s RMP.

SVII.3.2. Presentation of the Missing Information

Not applicable as this RMP for sildenafil follows the same safety concerns of the approved Viatrix’s RMP.

Part II: Module SVIII - Summary of the Safety Concerns

Table 3: SVIII- Summary of safety concerns

Important Identified Risks	• Vaso-occlusive crisis in patients with sickle cell disease • Increased relative mortality in the paediatric population • Bleeding events (excluding epistaxis)
Important Potential Risks	• Non-arteritic anterior ischaemic optic neuropathy (NAION) • Pulmonary haemorrhage in paediatric patients
Missing Information	• Long-term ocular safety • Safety in pregnancy

PART III: PHARMACOVIGILANCE PLAN (INCLUDING POST-AUTHORISATION SAFETY STUDIES)

The Pharmacovigilance System Master File contains details of the system and processes that the MAH/Applicant has in place to identify and/or characterize the risks recognised in the safety specification.

III.1 Routine Pharmacovigilance Activities

Routine pharmacovigilance activities only.

III.2 Additional Pharmacovigilance Activities

As current routine pharmacovigilance activities are sufficient, no additional pharmacovigilance activities are recommended.

III.3 Summary Table of Additional Pharmacovigilance Activities

None.

PART IV: PLANS FOR POST-AUTHORISATION EFFICACY STUDIES

Not applicable.

PART V: RISK MINIMISATION MEASURES (INCLUDING EVALUATION OF THE EFFECTIVENESS OF RISK MINIMISATION ACTIVITIES)

The safety information in the proposed product information is aligned to the reference medicinal product (Revatio by Pfizer).

Risk Minimisation Plan

V.1 Routine Risk Minimisation Measures

Table 4: Part V.1- Description of routine risk minimisation measures by safety concern

Safety Concern	Routine Risk Minimisation Activities
Vaso-occlusive crisis in patients with sickle cell disease	<u>Routine risk communication:</u> SmPC section 4.4 PL section 2 <u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u> None. <u>Other risk minimisation measures beyond the Product Information:</u> Medicine's legal status: prescription only medicine (POM).
Increased relative mortality in the paediatric population	<u>Routine risk communication:</u> SmPC section 4.2, 4.4 and 5.1 PL section 3 <u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u> SmPC Sections 4.2 ,4.4 and 5.1 state that higher than recommended doses should not be used in paediatric patients with PAH <u>Other risk minimisation measures beyond the Product Information:</u> Medicine's legal status: prescription only medicine (POM)
Bleeding events (excluding epistaxis)	<u>Routine risk communication:</u> SmPC section 4.4, 4.8 PL section 2 and 4 <u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u> Section 4.4 states that because there is no safety information on the administration of sildenafil to patients with bleeding disorders or active peptic ulceration, sildenafil should be administered to patients only after careful benefit-risk assessment. <u>Other risk minimisation measures beyond the Product Information:</u> Medicine's legal status: prescription only medicine (POM)

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Safety Concern	Routine Risk Minimisation Activities
Important potential risks	
Non-arteritic anterior ischaemic optic neuropathy (NAION)	<u>Routine risk communication:</u> SmPC section 4.3, 4.4 and 4.8 PL section 2 and 4 <u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u> Contraindication for patients who have loss of vision in one eye because of NAION, regardless of whether the episode was in connection or not with previous PDE5 inhibitor exposure is included in SmPC Section 4.3. Recommendation that in the event of any sudden visual defect, the treatment should be stopped immediately, and alternative treatment should be considered is included in SmPC Section 4.4., PL Section 2 and PL Section 4. <u>Other risk minimisation measures beyond the Product Information:</u> Medicine's legal status: prescription only medicine (POM)
Pulmonary haemorrhage in paediatric patients	<u>Routine risk communication:</u> None <u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u> None. <u>Other risk minimisation measures beyond the Product Information:</u> Medicine's legal status: prescription only medicine (POM)
Missing information	
Long-term ocular safety	<u>Routine risk communication:</u> None <u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u> None. <u>Other risk minimisation measures beyond the Product Information:</u> Medicine's legal status: prescription only medicine (POM)
Safety in pregnancy	<u>Routine risk communication:</u> SmPC section 4.6 PL section 2 <u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u> SmPC Section 4.6 states that due to the lack of data, Mylsildecard should not be used in pregnant women unless strictly necessary.

Safety Concern	Routine Risk Minimisation Activities
	Other risk minimisation measures beyond the Product Information: Medicine's legal status: prescription only medicine (POM)

V.2 Additional Risk Minimisation Measures

Routine risk minimisation activities are sufficient to manage the safety concerns of the medicinal product.

V.3 Summary Table of Pharmacovigilance and Risk Minimisation Activities by Safety Concern

Table 5: Part V.3- Summary table of pharmacovigilance activities and risk minimisation activities by safety concern

Safety Concern	Risk Minimisation Measures	Pharmacovigilance Activities
Vaso-occlusive crisis in patients with sickle cell disease	<u>Routine risk minimisation measures:</u> SmPC Section 4.4 PL Section 2 <u>Additional risk minimisation measures:</u> None	<u>Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:</u> None <u>Additional pharmacovigilance activities:</u> None
Increased relative mortality in the paediatric population	<u>Routine risk minimisation measures:</u> SmPC Section 4.2, 4.4, 5.1 PL Section 3 <u>Additional risk minimisation measures:</u> None	<u>Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:</u> None <u>Additional pharmacovigilance activities:</u> None
Bleeding events (excluding epistaxis)	<u>Routine risk minimisation measures:</u> SmPC Section 4.4, 4.8 PL Section 2, 4 <u>Additional risk minimisation measures:</u> None	<u>Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:</u> None <u>Additional pharmacovigilance activities:</u> None
Important Potential Risks		
Non-arteritic anterior ischaemic optic neuropathy (NAION)	<u>Routine risk minimisation measures:</u> SmPC Section 4.3, 4.4, 4.8 PL Section 2 and 4 <u>Additional risk minimisation measures:</u> None	<u>Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:</u> None <u>Additional pharmacovigilance activities:</u> None

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Safety Concern	Risk Minimisation Measures	Pharmacovigilance Activities
Pulmonary haemorrhage in paediatric patients	<u>Routine risk minimisation measures:</u> None <u>Additional risk minimisation measures:</u> None	<u>Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:</u> None <u>Additional pharmacovigilance activities:</u> None
Missing information		
Long-term ocular safety	<u>Routine risk minimisation measures:</u> None <u>Additional risk minimisation measures:</u> None	<u>Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:</u> None <u>Additional pharmacovigilance activities:</u> None
Safety in pregnancy	<u>Routine risk minimisation measures:</u> SmPC Section 4.6 PL Section 2 <u>Additional risk minimisation measures:</u> None	<u>Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:</u> None <u>Additional pharmacovigilance activities:</u> None

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Mysildecard (sildenafil)

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

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

This summary of the RMP for Mysildecard should be read in the context of all the 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 Mysildecard's RMP.

I. The Medicine and What it is Used For

Mysildecard is indicated for treatment of adult patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease and for treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease. It contains sildenafil as the active substance, and it is given by oral route of administration.

Further information about the evaluation of Mysildecard's benefits can be found in Mysildecard'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 Mysildecard, together with measures to minimise such risks and the proposed studies for learning more about Mysildecard'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 public (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

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In addition to these measures, information about adverse events 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 Mysildecard is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Mysildecard are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely 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 Mysildecard. 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 6: Part VI.1- Summary of safety concerns

Important Identified Risks	• Vaso-occlusive crisis in patients with sickle cell disease • Increased relative mortality in the paediatric population • Bleeding events (excluding epistaxis)
Important Potential Risks	• Non-arteritic anterior ischaemic optic neuropathy (NAION) • Pulmonary haemorrhage in paediatric patients
Missing Information	• Long-term ocular safety • Safety in pregnancy

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 Mysildecard.

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

There are no studies required for Mysildecard.

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Annex 4 - Specific Adverse Drug Reaction Follow-up Forms

Not applicable.

Annex 6 - Details of Proposed Additional Risk Minimisation Activities (If Applicable)

Not applicable.