EU Risk Management Plan Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma (tapentadol)

RMP version to be assessed as part of this application:

RMP Version number: 4.0

Data lock point for this RMP: 23-May-2025

Date of final sign-off:

Rationale for submitting an updated RMP: This RMP was updated according the comments from the Swedish authority (RMS), received on 2025-05-23.

Summary of significant changes in this RMP:

Part I: Product Overview in accordance with the updated SmPC.

Other RMP versions under evaluation: Not applicable

Details of the current approved RMP:

Version number: 2.0

Approved with procedures: SE/H/2160/001-006/DC; SE/H/2161/001-006/DC

Date of approval (opinion date): 21-April-2022

QPPV name:

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Part I: Product overview

Table Part I.1 – Product(s) Overview

Active substance(s) (INN or common name)	Tapentadol
Pharmaco-therapeutic group (ATC Code)	Other opioids (N02AX06)
Marketing Authorisation Holders	SE/H/2160/001-006/DC: G.L. Pharma GmbH Medical Valley Invest AB SE/H/2161/001-006/DC: Medical Valley Invest AB G.L. Pharma GmbH Laboratorios Liconsa, S.A.
Medicinal products to which this RMP refers	Six (06)
Invented name(s) in the European Economic Area (EEA)	SE/H/2160/001-006/DC: Tapentadol Depot G.L. Pharma SE/H/2161/001-006/DC: Tapentadol Depot Medical Valley
Marketing authorisation procedure	Decentralised
Hyperlink to the Product Information	Section 1.3 of product information of the dossier
Brief description of the product	Chemical class: Benzene and substituted derivatives Summary of mode of action: Tapentadol is a strong analgesic with μ-agonistic opioid and additional noradrenaline reuptake inhibition properties. Tapentadol exerts its analgesic effects directly without a pharmacologically active metabolite. Important information about its composition: Not applicable
Indication(s) in the EEA	Current: management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics. Proposed: – severe chronic pain in adults, which can be adequately managed only with opioid analgesics – severe chronic pain in children over 6 years of age and adolescents, which can be adequately

	managed only with opioid analgesics
Dosage in the EEA	Current: The dosing regimen should be individualised according to the severity of pain being treated, the previous treatment experience and the ability to monitor the patient. It should be taken twice daily, approximately every 12 hours. Proposed: Not applicable
Pharmaceutical form(s) and strengths	Current: 25, 50, 100, 150, 200 and 250 mg prolonged-release tablets Proposed: Not applicable
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

Not applicable for generic applications.

Part II: Module SII - Non-clinical part of the safety specification

Not applicable for generic applications.

Part II: Module SIII - Clinical trial exposure

Not applicable for generic applications.

Part II: Module SIV - Populations not studied in clinical trials

Not applicable for generic applications.

Part II: Module SV - Post-Authorisation Experience

Not applicable.

Part II: Module SVI - Additional EU requirements for the safety specification

Not applicable for generic applications.

Part II: Module SVII - Identified and potential risks

Not applicable.

Part II: Module SVIII - Summary of safety concerns

Table SVIII.1: Summary of safety concerns

Summary of safety concerns	
Important identified risks	Drug abuse and drug dependence
Important potential risks	None
Missing information	None

Part III: Pharmacovigilance Plan (including post-authorisation safety studies)

III.1 Routine pharmacovigilance activities

Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: none.

Specific adverse reaction follow-up questionnaires: None

Other forms of routine pharmacovigilance activities: None

III.2 Additional pharmacovigilance activities

No additional pharmacovigilance activities are required to assess effectiveness of risk minimisation measures.

III.3 Summary Table of additional Pharmacovigilance activities

Not applicable.

Part IV: Plans for post-authorisation efficacy studies

Not applicable.

Part V: Risk minimisation measures (including evaluation of the effectiveness of risk minimisation activities)

Risk Minimisation Plan

The safety information in the product information is aligned to the reference medicinal product.

V.1. Routine Risk Minimisation Measures

Not applicable.

V.2. Additional Risk Minimisation Measures

Not applicable.

V.3. Summary of risk minimisation measures

Not applicable.

Part VI: Summary of risk management plan

Summary of risk management plan for Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma (tapentadol)

This is a summary of the risk management plan (RMP) for Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma. The RMP details important risks of Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma and how more information will be obtained about Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma's risks and uncertainties (missing information).

Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma should be used.

Important new concerns or changes to the current ones will be included in updates of Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma's RMP.

I. The medicine and what it is used for

Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma is authorized for:

- severe chronic pain in adults, which can be adequately managed only with opioid analgesics
- severe chronic pain in children over 6 years of age and adolescents, which can be adequately managed only with opioid analgesics (see SmPC for the full indication)

It contains tapentadol as the active substance, and it is given by oral route.

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

Important risks of Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma, together with measures to minimise such 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, 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 Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma are risks that need special risk management activities to further investigate or minimise the risks, 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 Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma. 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	Drug abuse and drug dependence
Important potential risks	None
Missing information	None

II.B Summary of important risks

The safety information in the 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 authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma.

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

There are no studies required for Tapentadol Depot Medical Valley and Tapentadol Depot G.L. Pharma.

Part VII: Annexes

Annex 1 – EudraVigilance Interface

Not applicable.

Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme

Not applicable.

Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan

Not applicable.

Annex 4 - Specific adverse drug reaction follow-up forms

Not applicable.

Annex 5 - Protocols for proposed and on-going studies in RMP part IV

Not applicable.

Annex 6 - Details of proposed additional risk minimisation activities

Not applicable.

Annex 7 - Other supporting data (including referenced material)

Not applicable.

Annex 8 – Summary of changes to the risk management plan over time

Version	Approval date Procedure	Change
1.0	Approval date: Not approved Procedures: SE/H/2160/001-006/DC SE/H/2161/001-006/DC	First Marketing Authorization Application.
2.0	Approval date: 21-April-2022 Procedures: SE/H/2160/001-006/DC SE/H/2161/001-006/DC	This RMP V 2.0 was updated according to RMS Day 70 Preliminary Assessment Report, dated 21-July-2021. Summary of significant changes in this RMP: – Part II: Module SVIII - Summary of safety concerns: “Drug abuse and drug dependence” was included as an important identified risk – Part III: Pharmacovigilance Plan (including post-

		authorisation safety studies) – Part VI: Summary of risk management plan
3.0	Approval date: Pending Procedures: SE/H/2160/001-006/DC SE/H/2161/001-006/DC	This RMP was updated to align the indication with the reference medicinal product. Summary of significant changes in this RMP: - Part I: Product(s) Overview: update of Chemical class to 'Benzene and substituted derivatives'; indication update - Part V: Risk minimisation measures (including evaluation of the effectiveness of risk minimisation activities): inclusion of all subsections
4.0	Approval date: Pending Procedures: SE/H/2160/001-006/DC SE/H/2161/001-006/DC	This RMP was updated according the comments from the Swedish authority (RMS), received on 2025-05-23. Summary of significant changes in this RMP: Part I: Product Overview in accordance with the updated SmPC.