Summary of the Risk Management Plan (RMP) for Palexia®, Palexia® retard, Palexia® 4 mg/ml and 20 mg/ml Lösung zum Einnehmen

(INN: tapentadol)

Marketing Authorisation Holder:

Grünenthal GmbH (Decentralised European Procedure – DE/H/2020/001-011/DC)

Grünenthal Pharma AG (National procedures 62452, 62841, 60530)

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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 risks as well as to prevent or minimise them.

The RMP summary of "Bezeichnung des Arzneimittels" 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 "Bezeichnung des Arzneimittels" in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. "Name of the marketing authorisation holder" is fully responsible for the accuracy and correctness of the content of the published summary RMP of "Bezeichnung des Arzneimittels".

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

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

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

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

I. The medicine and what it is used for

Tapentadol film-coated tablet (FCT; immediate release)/oral solution is indicated for the relief of moderate to severe acute pain. Tapentadol prolonged-release tablet (PRT) is indicated for the management of severe chronic pain in adults, adolescents and children above 6 years, which can be adequately managed only with opioid analgesics. Tapentadol oral solution is indicated for relief of moderate to severe acute pain in children from 2 years of age, adolescents and adults, which can be adequately managed only with opioids (see SmPC for the full indication).

All three formulations contain tapentadol hydrochloride as the active substance and are given by the oral route.

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

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

II.A List of important risks and missing information

Important risks of tapentadol are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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. 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

Drug abuse and drug dependence	
Evidence for linking the risk to the medicine	The source of evidence is the established class effect for compounds with mu-opioid activity. For details refer to the description of pharmacological class effects (Part II.SVII.1 of the EU RMP).
Risk factors and risk groups	Generally, multiple factors, such as personal, familiar and social ones play a role in individual susceptibility for drug abuse, including personal history of substance abuse, family history of substance abuse, psychological stress/trauma/illness, psychotropic substance use, nonfunctional status due to pain or exaggeration of pain, young age, smoking, poor social support, preadolescent sexual abuse and legal problems (Webster 2017). The risk of abuse also increases over time, when individuals begin consuming larger doses and is more likely associated with immediate release formulations than extended-release ones (Smith 2011).
Risk minimisation measures	• Routine risk communication: Warning in Section 4.4 in SmPC • Routine risk minimisation activities recommending specific clinical measures to address the risk: Not applicable • Other routine risk minimisation measures: Prescription only medicine classified as a controlled drug at national levels providing a restricted access complying with the schedule I of the United Nations Convention on Narcotic Drugs.

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 authorization of tapentadol.

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

There are no studies required for tapentadol.