Part VI: Summary of the risk management plan

Summary of risk management plan for Tapentadol Vivanta 25mg, 50 mg, 100 mg, 150 mg, 200 mg, 250 mg Prolonged Release Tablets (Tapentadol)

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

Tapentadol Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) 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 the Tapentadol RMP.

I. The medicine and what it is used for

Tapentadol is authorised for the management of:

- severe chronic pain in adults, which can be adequately managed only with opioid analgesics.
- severe chronic pain in children above 6 years and adolescents, which can be adequately managed only with opioid analgesics.

The tablets contain Tapentadol as the active substance and are given by oral route of administration.

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 25 mg, 50 mg, 100 mg, 150 mg, 200 mg, 250 mg Prolonged Release Tablets 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 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);

Summary of safety concerns	
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 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 Tapentadol.

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

There are no studies required for Tapentadol.