

## Part VI: Summary of the risk management plan

### Summary of risk management plan for Tapentadol G.L. film-coated tablets (tapentadol)

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

*Tapentadol G.L. film-coated tablets'* summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how *Tapentadol G.L. film-coated tablets* should be used.

Important new concerns or changes to the current ones will be included in updates of *Tapentadol G.L. film-coated tablets'* RMP.

#### I. The medicine and what it is used for

*Tapentadol G.L. film-coated tablets* are indicated for the relief of moderate to severe acute pain in adults, which can only be adequately managed with opioid analgesics. *Tapentadol G.L. film-coated tablets* contain tapentadol as the active substance and the tablets are given orally. *Tapentadol G.L. film-coated tablets* are available in strengths of 25 mg, 50 mg, 75 mg and 100 mg.

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

Important risks of *Tapentadol G.L. film-coated tablets*, together with measures to minimise such risks and the proposed studies for learning more about *Tapentadol G.L. film-coated 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 G.L. film-coated tablets* 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 *Tapentadol G.L. film-coated tablets*. 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	Potential for medication errors with tapentadol oral solution
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 G.L. film-coated tablets*.

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

There are no studies required for *Tapentadol G.L. film-coated tablets*.