Part VI: Summary of the risk management plan

Summary of risk management plan for Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and 'Oxycodone 5 mg, 10 mg, 20 mg capsules, hard' (Oxycodone hydrochloride)

This is a summary of the risk management plan (RMP) for 'Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and 'Oxycodone 5 mg, 10 mg, 20 mg capsules, hard'. The RMP details important risks of 'Oxycodone 5 mg, 10 mg and 20 mg capsules, hard'; how these risks can be minimised, and how more information will be obtained about 'Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and Oxycodone 5 mg, 10 mg, 20 mg capsules, hard' risks and uncertainties (missing information).

Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and Oxycodone 5 mg, 10 mg and 20 mg capsules, hard' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and Oxycodone 5 mg, 10 mg and 20 mg capsules, hard' should be used.

Important new concerns or changes to the current ones will be included in updates of Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and Oxycodone 5 mg, 10 mg and 20 mg capsules, hard' RMP.

I. The medicine and what it is used for

Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and Oxycodone 5 mg, 10 mg and 20 mg capsules, hard' is indicated for the treatment of severe pain, which can be adequately managed only with opioid analgesics. Oxycodone hydrochloride is indicated in adults and adolescents of 12 years and older.

It contains oxycodone hydrochloride as the active substance and given by oral route.

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

Important risks of Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and Oxycodone 5 mg, 10 mg and 20 mg capsules, hard', together with measures to minimise such risks and the proposed studies for learning more about Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and Oxycodone 5 mg, 10 mg and 20 mg capsules, hard' 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 during signal management activity, 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 Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and Oxycodone 5 mg, 10 mg and 20 mg capsules, hard' 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 Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and Oxycodone 5 mg, 10 mg and 20 mg capsules, hard'. 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);

Important identified risks	• Respiratory depression • Drug dependence and withdrawal • Abuse and misuse and diversion
Important potential risks	•
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 authorization or specific obligation of Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and Oxycodone 5 mg, 10 mg and 20 mg capsules, hard'.

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

There are no studies required for Oxycodone Prolonged-release tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg and Oxycodone 5 mg, 10 mg and 20 mg capsules, hard'.