Part VI: Summary of the risk management plan

Summary of risk management plan for Oxycodone/Naloxone Nordic Drugs Drugs 5 mg/2,5 mg depottabletter, Oxycodone/Naloxone Nordic Drugs 10 mg/5 mg depottabletter, Oxycodone/Naloxone Nordic Drugs 20 mg/10 mg depottabletter, Oxycodone/Naloxone Nordic Drugs 30 mg/15 mg depottabletter and Oxycodone/Naloxone Nordic Drugs 40 mg/20 mg depottabletter (Oxycodone hydrochloride / Naloxone hydrochloride dihydrate)

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

Oxycodone/Naloxone Nordic Drugs' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Oxycodone/Naloxone Nordic Drugs should be used.

Important new concerns or changes to the current ones will be included in updates of Oxycodone/Naloxone Nordic Drugs' RMP.

I. The medicine and what it is used for

Oxycodone/Naloxone Nordic Drugs is authorised for use in adults for severe pain, which can be adequately managed only with opioid analgesics (see SmPC for the full indication). It contains oxycodone hydrochloride and naloxone hydrochloride dihydrate as the active substances and it is administered orally.

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

Important risks of Oxycodone/Naloxone Nordic Drugs, together with measures to minimise such risks and the proposed studies for learning more about Oxycodone/Naloxone Nordic Drugs' risks, are outlined below.

Measures to minimise the risks identified for medicinal product are:

- 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, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Oxycodone/Naloxone Nordic Drugs is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Oxycodone/Naloxone Nordic Drugs 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 Oxycodone/Naloxone Nordic Drugs. 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	• Respiratory depression • Drug dependence and drug withdrawal syndrome • Overdose • Medication error • Constipation • Diarrhoea
Important potential risks	• Drug abuse, misuse and diversion • Hepatic disorders • Increased risk of withdrawal or overdose in patients with hepatic or renal failure
Missing information	• Use in paediatric patients <18 years • Use in pregnant and breastfeeding women • Off label use

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 Oxycodone/Naloxone Nordic Drugs.

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

There are no studies required for Oxycodone/Naloxone Nordic Drugs.