Part VI: Summary of the risk management plan

Summary of risk management plan for Oxycodone/Naloxone Stada 60 mg/30 mg and 80 mg/40 mg prolonged-release tablets (Oxycodone-HCl/Naloxone-HCl)

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

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

I. The medicine and what it is used for

Oxycodone/Naloxone Stada is authorised in adults for severe pain, which can be adequately managed only with opioid analgesics. The opioid antagonist naloxone is added to counteract opioid-induced constipation by blocking the action of oxycodone at opioid receptors locally in the gut (see SmPC for the full indication). It contains oxycodone-HCl and naloxone-HCl as the active substances and it is given orally.

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

Important risks of Oxycodone/Naloxone Stada, together with measures to minimise such risks and the proposed studies for learning more about Oxycodone/Naloxone Stada'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 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.

If important information that may affect the safe use of Oxycodone/Naloxone Stada 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 Stada 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/ Naloxone Stada. 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	• 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 • Long-term treatment (>12 months) in RLS • 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 Stada.

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

There are no studies required for Oxycodone/Naloxone Stada.