

Summary of risk management plan for Oxycodone Abboxia 1 mg/ml solution for injection / infusion and Oxycodone Abboxia 10 mg/ml solution for injection / infusion (oxycodone hydrochloride)

This is a summary of the risk management plan (RMP) for Oxycodone Abboxia, solution for injection/infusion (1 mg/ml or 10 mg/ml). The RMP details important risks of Oxycodone Abboxia, solution for injection/infusion, how these risks can be minimised, and how more information will be obtained about Oxycodone Abboxia, solution for injection/infusion's risks and uncertainties (missing information).

Oxycodone Abboxia, solution for injection/infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Oxycodone Abboxia, solution for injection/infusion should be used.

I. The medicine and what it is used for

Oxycodone Abboxia, solution for injection/infusion is authorised for the treatment of acute pain (e.g., postoperative pain), cancer pain or other chronic pain (see SmPC for full indication). It contains oxycodone hydrochloride as the active substance, and it is given by intravenous, intramuscular or subcutaneous route of administration.

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

Important risks of Oxycodone Abboxia, solution for injection/infusion, together with measures to minimise such risks and the proposed studies for learning more about Oxycodone Abboxia, solution for injection/infusion'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.

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 Oxycodone Abboxia, solution for injection/infusion 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 Abboxia, solution for injection/infusion. 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 | None |
| 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 Oxycodone Abboxia, solution for injection/infusion.

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

There are no studies required for Oxycodone Abboxia, solution for injection/infusion.