

Summary of risk management plan for Oxycodone

This is a summary of the RMP for Oxycodone. The RMP details important risks of Oxycodone, how these risks can be minimized, and how more information will be obtained about Oxycodone's risks and uncertainties (missing information).

The Summary of Product Characteristics (SmPC) and package leaflet of Oxycodone give essential information to healthcare professionals and patients on how Oxycodone should be used.

This summary of the RMP for Oxycodone should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all of which is part of the European Public Assessment Report (EPAR). Important new concerns or changes to the current data will be included in updates of the Oxycodone RMP.

I. The medicine and what it is used for

Oxycodone is authorised for the treatment of severe pain and it is given by oral and intravenous routes.

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

Important risks of Oxycodone, together with measures to minimise such risks and the proposed studies for learning more about Oxycodone'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 is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Oxycodone 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. 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).

Table Part VI. 1: List of important risks and missing information

Important identified risks	Drug abuse Psychological dependence Accidental overdose Physical dependence and drug withdrawal syndrome (DWS)
Important potential risks	None
Missing information	Use in pregnant and lactating women

II.B Summary of important risks

Table Part VI. 2: Summary of important identified risks

Important identified risks	
Drug abuse	
Evidence for linking the risk to the medicine	International drug safety database search (worldwide data reported since DIBD).
Risk factors and risk groups	Risk factors include socio-demographic factors, pain and drug-related factors, genetics, environment, psychosocial and family history and alcohol and substance use disorders.
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.2 (Posology) SmPC Section 4.4 (Special Warnings and Precautions for Use) SmPC Section 4.8 (Undesirable Effects) Additional risk minimization measures: None
Psychological dependence	
Evidence for linking the risk to the medicine	International drug safety database search (worldwide data reported since DIBD).
Risk factors and risk groups	Risk factors include socio-demographic factors, pain and drug-related factors, genetics, environment, psychosocial and family history and alcohol and substance use disorders.
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.2 (Posology) SmPC Section 4.4 (Special Warnings and Precautions for Use) SmPC Section 4.8 (Undesirable Effects) Additional risk minimization measures: None
Physical dependence and drug withdrawal syndrome (DWS)	
Evidence for linking the risk to the medicine	International drug safety database search (worldwide data reported since DIBD).
Risk factors and risk groups	Risk factors include socio-demographic factors, pain and drug-related factors, genetics, environment, psychosocial and family history and alcohol and substance use disorders.
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.2 (Posology) SmPC Section 4.4 (Special Warnings and Precautions for Use) SmPC Section 4.8 (Undesirable Effects) Additional risk minimization measures: None
Accidental overdose	
Evidence for linking the risk to the medicine	International drug safety database search (worldwide data reported since DIBD).
Risk factors and risk groups	Risk Factors - Co-administration with drugs that reduce the clearance of oxycodone hydrochloride, leading to an increase in plasma concentration - Co-administration with CNS depressants Risk groups - Patients with hepatic and renal impairment and co-administration of oxycodone hydrochloride with drugs that reduce the clearance of the drug, which leads to an increase in plasma concentration. - Patients who are abusing opioids are at risk of accidental

Table Part VI. 2: Summary of important identified risks

Important identified risks	
	overdose.
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.2 (Posology) SmPC Section 4.4 (Special Warnings and Precautions for Use) SmPC Section 4.9 (Overdose) Additional risk minimization measures: None

Table Part VI. 3: Summary of important identified risks

Important potential risks	
None	

Table Part VI. 4: Missing information

Missing information	
Use in pregnant and lactating women	
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.6 (Fertility, pregnancy and lactation) Additional risk minimization measures: None