VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Pain is often a protective function of the body, shielding it from damage and overload. Acute pain is one of the most common health problems. Its duration is usually limited (up to 6 weeks). Due to the marked high frequency associated with many diseases, there is hardly any information available on the frequency of acute pain.
Severe, chronic pain is defined as disabling condition that has lasted longer than three to six months. Common chronic pain complaints include cancer pain, arthritis pain, and neurogenic pain (pain resulting from damage to the peripheral nerves or to the central nervous system itself). Chronic pain conditions affect older adults and are more common in women. A recent market research report indicates that more than 1.5 billion people worldwide suffer from chronic pain and that approximately 3- 4.5% of the global population suffers from neuropathic pain, with incidence rate increasing in complementary to age.

VI.2.2 Summary of treatment benefits

Based on the available data from clinical studies and clinical experience of several years, oxycodone represents an effective drug in management of severe pain, which can only be adequately managed with opioid analgesics.

If administered as indicated in the Summary of Product Characteristics and taking into account the contra-indications, the warnings and precautions, oxycodone can be considered effective in the approved indications.

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Severely depressed breathing **(Respiratory depression)**	Severely depressed breathing is the most significant risk induced by group of drugs called opioids and is most likely to occur in elderly or weak patients. Drinking alcohol whilst taking oxycodone hydrochloride may increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. Use of oxycodone during childbirth can cause breathing problems in the newborn.	Do not take oxycodone hydrochloride if you suffer from severely depressed breathing (respiratory depression) with too little oxygen in the blood (hypoxia) and/or too much carbon dioxide (hypercapnia) in the blood. Talk to your doctor or pharmacist before taking oxycodone hydrochloride if you are older or debilitated. It is recommended that you do not drink alcohol while you are taking oxycodone hydrochloride.
Tolerance, dependence and withdrawal syndrome with prolonged use	Oxycodone hydrochloride has a primary dependence potential. When used for a long time, tolerance to the effects may develop and progressively higher doses may be required to maintain pain control. Chronic use of oxycodone hydrochloride may lead to physical dependence and a withdrawal syndrome may occur if you suddenly stop taking this medicine. Prolonged use of oxycodone during pregnancy can cause withdrawal symptoms in newborns.	When you no longer require therapy with oxycodone hydrochloride, it may be advisable to reduce the dose gradually to prevent symptoms of withdrawal. To avoid withdrawal symptoms in the newborn, you should avoid oxycodone hydrochloride during pregnancy if possible.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Use in children under 12 years of age	Oxycodone hydrochloride is NOT recommended for use in children under 12 years of age as the safety and efficacy have not been established.
Abuse / misuse	Abuse of high doses of strong opioids such as oxycodone can be fatal. Oxycodone hydrochloride should be used with particular care in patients with a history of or present alcohol and drug abuse.

Missing information

N/A

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Not applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not applicable.