

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Oxycodone hydrochloride is a strong pain killer used for treatment of moderate to severe pain. It is believed that globally 1 in 5 adults suffer from pain and one in five Europeans suffer from moderate to severe chronic pain. Pain can be broadly classified into non-cancer and cancer pain. In Europe, 12 to 25 out of 100 individuals suffer from non-cancer related pain. Pain is one of the most common symptoms of cancer and affects an estimated third of patients receiving cancer treatment. A survey conducted in 15 European countries and Israel, found that on the country level, cancer types with the highest pain were reported to be the in Switzerland, Israel, Italy, UK, France and Ireland. With regards to demographics, 18 out of 100 young adults experience non-cancer pain which increases to 30 to 65 out of 100 adults aged 55-65 years and 25 to 55 of 100 adults over 85 years. A classification of the age groups in cancer pain depends on the type of the cancer an individual experiences. Pain can be treated by selecting proper drugs and pain-killers. The selection of the drugs depends on how severe the pain is.

Chronic pain represented by condition such as low back pain and osteoarthritis is one of the most common debilitating conditions encountered by healthcare professionals, particularly among older (≥65 years) patients. Pain is associated with substantial disability from reduced mobility, avoidance of activity, falls, depression and anxiety, sleep impairment, and isolation. Its negative effects extend beyond the patient, to disrupt both family and social relationships. The estimated prevalence of chronic pain in the UK is 43% corresponding to just under 28 million people. A trend towards increasing prevalence of pain (chronic widespread pain, chronic neuropathic pain and fibromyalgia) with increasing age from 14.3% in 18-25 years old, to 62% in the over 75 age group was shown, although the prevalence of chronic pain in young people (18-39 years old) may be as high as 30%. Chronic pain is more common in women than in men. Chronic pain poses a significant economic burden on society. Prevalence rates for pain are expected to increase as populations continue to age—by 2035 an estimated one quarter of the population in the European Union will be 65 or older—thereby increasing the public health impact of pain.

References:

1. Public summary of the OxyNorm/OxyContin RMP (Version 8.0 dated 16-Feb-2015) by Napp Pharmaceuticals Ltd published on Danish Medicine Agency website:
<https://laegemiddelstyrelsen.dk/upload/rmp/28103115799%2028103115899%2028103129499%2028103129599%2028103129699%2028103336101%2028104053706%2028104053806%2028104053906%2028105085712%2017-07-2015.pdf>
2. Reid MC, Eccleston C, Pillemer K. Management of chronic pain in older adults. *BMJ* 2015;350:h532
3. Fayaz A, Croft P, Langford RM, Donaldson LJ, Jones GT. Prevalence of chronic pain in the UK: a systematic review and meta-analysis of population studies. *BMJ* 2016 6:e010364. doi:10.1136/bmjopen-2015-010364

VI.2.2 Summary of treatment benefits

This Oxycodone hydrochloride injection is used to relieve moderate to severe pain. It contains the active ingredient oxycodone which belongs to a group of medicines called strong analgesics or ‘painkillers’.

VI.2.3 Unknowns relating to treatment benefits

Information regarding use of oxycodone hydrochloride in pregnant and lactating women is very limited. Also information on administration in unlicensed populations like in children and adolescents below 18 years of age is limited.

VI.2.4 Summary of safety concerns

The medicinal product is usually administered in a hospital setting or under controlled conditions where the patient receiving the medication is closely monitored by healthcare professionals. This medicinal product is available only on a special medical prescription and is subject to a tightly controlled supply chain.

Important identified risk		
Risk	What is known	Preventability
Drug tolerance, dependence (psychological dependence) and withdrawal syndrome (physical dependence)	As with all strong painkillers that are given for a prolonged period of time, there is a risk that the patients will need higher doses to control the pain and may become addicted to, or reliant on oxycodone. If the treatment is stopped suddenly this may cause withdrawal symptoms such as: agitation, anxiety, palpitations, sweating and shaking. Use of oxycodone during pregnancy can cause withdrawal symptoms in newborns.	Therapy with oxycodone should be avoided in patients with a history of alcohol or drug abuse. Treatment with oxycodone should not be stopped suddenly and the dose should be reduced gradually to avoid any unpleasant symptoms. The patient or patient's carer should seek a doctor's advice on the dose tapering schedule when therapy with oxycodone is considered no longer needed. The use of oxycodone during pregnancy should be avoided.
Drug abuse and misuse (not receiving the medicine as it was prescribed/ recommended by the doctor)	If oxycodone is given or taken not as it was directed/ instructed by the doctor this can result in serious side effects including overdosing which can be fatal.	Therapy with oxycodone should be avoided in patients with a history or alcohol or drug abuse. It is important to be given the precise dose of oxycodone at specified intervals as it was prescribed by the doctor. It is important to follow all the directions specified on the label attached to the medicine.
Accidental or intentional overdose (being given too much of the medicine)	If the patient is given more oxycodone than was prescribed this may cause symptoms such as: feeling sleepy, sick, dizzy or having hallucinations. Sometimes breathing difficulties may appear which lead to unconsciousness and death. In serious cases emergency treatment at the hospital is needed.	If higher than recommended dose is given to the patient and/or overdose symptoms are present, immediate medical attention should be sought by contacting the doctor or emergency treatment at the hospital is required. A drug which reverses the oxycodone effect should be given. Oxycodone should always be

		given as per doctor's recommendation. The label on the medicine states the exact doses and time the medicine should be given. The dose prescribed by the doctor must not be exceeded.
Respiratory depression (breathing more slowly and weakly than normally)	<p>If oxycodone is given at doses higher than recommended by a doctor, respiratory depression (breathing difficulties) may occur. This serious condition which might be life-threatening involves breathing really slowly and more weakly than expected.</p> <p>Drinking alcohol while receiving oxycodone may increase the risk of breathing difficulties such as shallow breathing with a risk of stopping breathing and loss of consciousness.</p> <p>Use of oxycodone in pregnant women can cause breathing problems in newborns.</p>	<p>If the symptoms of respiratory depression /overdose appear, the patient should seek immediate medical attention. A drug that reverses the effect of oxycodone might be given to the patient.</p> <p>It is important to be given the precise dose of oxycodone at specified intervals as it was prescribed by the doctor.</p> <p>Oxycodone injection should not be given to patients with existing breathing problems (examples include: chronic obstructive pulmonary disease, asthma). It is strongly recommended not to drink alcohol while on therapy with oxycodone.</p> <p>The use of oxycodone during pregnancy should be avoided.</p>
Central nervous system depression (concomitant use with alcohol and certain drugs may cause difficulties in breathing and may affect your concentration and perception)	<p>Oxycodone should not be given with alcohol and other medicines affecting the central nervous system (such as tranquillisers, anaesthetics, sedatives, hypnotics, other opioids, antidepressants, muscle relaxants, neuroleptic drugs, phenothiazines, antihypertensive) since the side effects of oxycodone may worsen.</p> <p>Drinking alcohol while being given oxycodone may result in serious side effects like: feeling sleepy, shallow breathing with a risk of stopping breathing, loss of consciousness.</p>	<p>Patients who are on other medications taken for sleep problems (tranquillisers, hypnotics, sedatives) or for anxiety or to treat depression should consult a pharmacist or a doctor before being given oxycodone injection.</p> <p>While a patient is receiving oxycodone it is strongly recommended not to drink alcohol at the same time.</p>
Interactions with MAO inhibitors causing central nervous system excitation or depression with hypertensive or hypotensive crisis	<p>Oxycodone must not be given to patients who are on certain medicines that inhibit the enzyme monoamine oxidase (examples include the antidepressants moclobemide, tranylcypromine, phenelzine, isocarboxazid and the antibiotic linezolid) or if any of these medicines have been taken in the last two weeks</p>	<p>Oxycodone injections must not be given to patients who currently are on monoamine oxidase inhibitors or who have been taken this type of medicine in the last two weeks.</p>

	prior to therapy with oxycodone. Serious interaction between oxycodone and these medicines may cause dangerous drop or rise of blood pressure.	
Use in patients with head injury	If oxycodone injection is given to patients with a head injury with severe headaches and feeling sick (risk of increased pressure in a skull) it may mask the extent of the injury and worsen the symptoms.	The use of oxycodone in patients with a head injury is contraindicated.
Use in patients with hepatic and renal impairment	If oxycodone injection is intended to be given to patients with liver or kidney problems special dose adjustments may be required and drug levels in blood should be carefully monitored during the time of the treatment.	Oxycodone injection should always be given at doses and frequency prescribed/ recommended by the doctor.
Use in patients with paralytic ileus (severe bowel obstruction)	Paralytic ileus (a severe form of bowel obstruction) can be caused by bowel surgery, pain, emotional stress, other medicines and anaesthetics.	Oxycodone injections are contraindicated in patients currently suffering from paralytic ileus (severe bowel obstruction), before and 12-24h after the surgery. Following the surgery oxycodone injection shouldn't be given until the doctor is assured of normal bowel function.

Important potential risk	
Risk	What is known
Abnormal heart rhythm (atrial fibrillation, supraventricular tachycardia)	Therapy with oxycodone hydrochloride may cause fast, irregular heart beat which is uncommon. Cardiac problems also can appear due to sudden discontinuation of oxycodone therapy.
Medications errors	Oxycodone hydrochloride Injection is administered to patients by healthcare professionals. However, cases of medication error associated with prescribing, dispensing or wrong dose administration of oxycodone hydrochloride injections have been reported. Patients should immediately talk to their doctor or nurse if they think they have been given more oxycodone hydrochloride injection than they should. The dosing schedule is individually established depending on the severity of pain, medical history, concurrent condition and a regular re-evaluation of the patient receiving the treatment with oxycodone is needed.

Constipation	Oxycodone therapy may cause constipation which is a common predictable side effect of strong painkillers, sometimes it may get really painful and even lead to dangerous bowel blockage. Oxycodone injections are contraindicated in patients having ongoing problems with constipation.
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Missing information	
Risk	What is known
Use in pregnant and lactating women	The effects of treatment during pregnancy is not well known. The use of oxycodone hydrochloride should be avoided in pregnant women as much as possible. Oxycodone injection may lead to respiratory depression and withdrawal syndrome in newborns if it was given to mothers during the last 3 to 4 weeks before giving birth. Patients who are pregnant or breast-feeding, who think they may be pregnant or are planning to have a baby, should ask their doctor or pharmacist for advice before being given this medicine. The doctor will then decide if treatment is suitable. Oxycodone hydrochloride passes into the milk and may cause respiratory depression in newborns. Hence it should not be used in breast feeding women.
Safety and efficacy of use in paediatric patients <18 years	The safety and effects of oxycodone treatment in children and adolescents below 18 years of age are not well known and oxycodone injections should not be given to these patients. Accidental overdose by a child is dangerous and might be fatal.

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 (PIL). 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

Version	Date	Safety concerns	Comment
1.0		N/A	New RMP