Package leaflet: Information for the user

Oxycodone Hydrochloride 10mg/ml Solution for Injection or Infusion

(referred to as Oxycodone Injection in this leaflet)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Oxycodone Injection is and what it is used for
2. What you need to know before you use Oxycodone Injection
3. How to use Oxycodone Injection
4. Possible side effects
5. How to store Oxycodone Injection
6. Contents of the pack and other information

1. What Oxycodone Injection is and what it is used for

This injection has been prescribed for you by your doctor to relieve moderate to severe pain. It contains the active ingredient oxycodone which belongs to a group of medicines called strong analgesics or 'painkillers'.

2. What you need to know before you use Oxycodone Injection

Do not use Oxycodone injection if you:
• are allergic (hypersensitive) to oxycodone, or any of the other ingredients of the injection (listed in section 6);
• have breathing problems, such as severe chronic obstructive lung disease, severe bronchial asthma or severe respiratory depression. Your doctor will have told you if you have any of these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
• have a condition where the small bowel does not work properly (paralytic ileus) or you have severe pain in your abdomen;
• have a heart problem after long-term lung disease (cor pulmonale);
• have moderate to severe liver problems. If you have other long-term liver problems you should only use this injection if recommended by your doctor;
• have ongoing problems with constipation;
• have elevated carbon dioxide levels in the blood.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before treatment with Oxycodone injection if you:
• are elderly or weakened;
• have an under-active thyroid gland (hypothyroidism), as you may need a lower dose;
• have myxoedema (a thyroid disorder with dryness, coldness and swelling ('puffiness') of the skin affecting the face and limbs;
• have a head injury, severe headache or feel sick as this may indicate that the pressure in your skull is increased;
• have low blood pressure (hypotension);
• have low blood volume (hypovolaemia); this can happen with severe external or internal bleeding, severe burns, excessive sweating, severe diarrhoea or vomiting;
• have a mental disorder as a result of an infection (toxic psychosis);
• have inflammation of the pancreas (which causes severe pain in the abdomen and back);
• have problems with your gall bladder or bile duct;
• have inflammatory bowel disease;
• have an enlarged prostate gland, which causes difficulty in passing urine (in men);
• have poor adrenal gland function (your adrenal gland is not working properly which may cause symptoms including weakness, weight loss, dizziness, feeling or being sick), e.g. Addison's disease;
• have breathing problems such as severe pulmonary disease. Your doctor will have told you if you have this condition. Symptoms may include breathlessness and coughing;

• have kidney or liver problems;
• have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking alcohol or drugs;
• are or have ever been addicted to alcohol or drugs or have a known opioid dependence;
• have an increased sensitivity to pain;
• need to use increasingly higher doses of Oxycodone to gain the same level of pain relief (tolerance).

If you are going to have an operation, please tell the doctor at the hospital that you are using this medicine.

You may experience hormonal changes while taking this medicine. Your doctor may want to monitor these changes.

Children and adolescents

Do not give this medicine to children under 18 years the potential benefits are not greater than the risks.

Other medicines and Oxycodone injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you use this injection with some other medicines, the effect of this injection or the other medicines may be changed.

Concomitant use of opioids and benzodiazepines increase the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe benzodiazepines or related drugs with opioids the dosage and duration of concomitant treatment should be limited by your doctor.

Please follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

The risk of side effects increases, if you use antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine). These medicines may interact with oxycodone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Tell your doctor or pharmacist if you are taking:
• a type of medicine known as a monoamine oxidase inhibitor or you have taken this type of medicine in the last two weeks;
• medicines to help you sleep or stay calm (for example hypnotics or sedatives, including benzodiazepines);
• medicines to treat depression (such as paroxetine);
• medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptics);
• other strong analgesics ('painkillers');
• muscle relaxants;
• medicines to treat high blood pressure.
• quinidine (a medicine to treat a fast heartbeat);
• cimetidine (a medicine for stomach ulcers, indigestion or heartburn);
• antifungal medicines (such as ketoconazole, voriconazole, itraconazole and posaconazole);
• antibiotics (such as clarithromycin, erythromycin or telithromycin);
• medicines known as 'protease inhibitors' to treat HIV (e.g. boceprevir, ritonavir, indinavir, nelfinavir or saquinavir);
• rifampicin (to treat tuberculosis);
• carbamazepine (a medicine treat seizures, fits or convulsions and certain pain conditions);
• phenytoin (a medicine to treat seizures, fits or convulsions);
• a herbal remedy called St. John's Wort (also known as *Hypericum perforatum*);
• antihistamines;
• medicines to treat Parkinson's disease;
• medicines to treat depression (antidepressants). The risk of side effects increases if you use antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine). These medicines may interact with oxycodone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Also tell your doctor if you have recently been given an anaesthetic.

Oxycodone Injection with food, drink and alcohol
Drinking alcohol during your treatment with this injection may make you sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you're using Oxycodone injection.

You should avoid drinking grapefruit juice during your treatment with this medicine.

Pregnancy and breast-feeding
Do not use this injection if you are pregnant or breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machinery
This injection may cause a number of side effects such as drowsiness which could affect your ability to drive or use machinery (see section 4 for a full list of side effects).
These are usually most noticeable when you first start using the injection, or when changing to a higher dose. If you are affected you should not drive or use machinery.

This medicine can affect your ability to drive.
Do not drive whilst using this medicine until you know how this medicine affects you.
It may be an offence to drive if your ability to drive safely is affected.
There is further information for patients who are intending to drive in Great Britain - go to:
http://www.gov.uk/drug-driving-law

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while using this medicine.

Oxycodone Injection contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How to use Oxycodone Injection

A doctor or nurse will usually prepare and administer the injection for you. The injection should be used immediately after opening. The dose and how often the injection is given may be adjusted according to the severity of your pain.

Adults (over 18 years of age)
The recommended starting dose is dependent upon how the injection is administered. The recommended starting doses are as follows:
• As a single injection into a vein, the recommended dose is 1 to 10 mg given slowly over 1 to 2 minutes. This can be repeated every 4 hours.
• As an infusion into a vein, the recommended starting dose is 2 mg/hour.
• As a single injection through a fine needle into the tissue under the skin, the recommended starting dose is 5 mg repeated at 4-hourly intervals if needed.
• As an infusion through a fine needle into the tissue under the skin, the recommended starting dose is 7.5 mg/day.
• If given by patient controlled analgesia (PCA), the dose is worked out according to your weight (0.03 mg per kg of body weight). Your doctor or nurse will set a suitable frequency.

Use in children
Not to be used in patients under 18 years of age

Elderly
The lowest dose needed for symptom control should be used.

Patients with kidney or liver problems
Please tell your doctor if you suffer from kidney or liver problems as they may prescribe a lower dose depending on your condition. The dose recommended by the doctor should not be exceeded. Check with the doctor or pharmacist if you are unsure.
If you find that you are still in pain whilst being given this injection discuss this with your doctor.

If you use more Oxycodone injection than you should, or if someone else uses your injection

Call your doctor or hospital straight away. People who have been given an overdose may feel very sleepy, sick or dizzy. They may also have breathing difficulties leading to unconsciousness or even death and may need emergency treatment in hospital.
When seeking medical attention make sure that you take this leaflet and any remaining injection with you to show to the doctor.

If you stop using Oxycodone Injection
You should not suddenly stop using this injection unless your doctor tells you to.
If you want to stop using your injection, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects. Withdrawal symptoms such as agitation, anxiety, palpitations, shaking or sweating may occur if you suddenly stop using this injection.

If you have any further questions on the use of this injection, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Oxycodone Injection can cause side effects, although not everybody gets them.
All medicines can cause allergic reactions, although serious allergic reactions are rare. **Tell your doctor immediately** if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.

The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression). **Tell your doctor immediately** if this happens to you.

As with all strong painkillers, there is a risk that you may become addicted or reliant on this injection.

Other possible side effects

Very common (May affect more than 1 in 10 people)
• Constipation (your doctor can prescribe a laxative to overcome this problem).
• Feeling or being sick (this should normally wear off after a few days, however your doctor can prescribe an anti-sickness medicine if it continues to be a problem).
• Drowsiness (this is most likely when you start using your medicine or when your dose is increased, but it should wear off after a few days).
• Dizziness.
• Headache.
• Itchy skin.

Common (May affect up to 1 in 10 people)
• Dry mouth, loss of appetite, indigestion, abdominal pain or discomfort, diarrhoea.
• Confusion, depression, a feeling of unusual weakness, shaking, lack of energy, tiredness, anxiety, nervousness, difficulty in sleeping, abnormal thoughts or dreams.
• Difficulty in breathing or wheezing, shortness of breath, decreased cough reflex.
• Rash.
• Sweating.

Uncommon (May affect up to 1 in 100 people)
• Difficulty in swallowing, belching, hiccups, wind, a condition where the bowel does not work properly (ileus), inflammation of the stomach, changes in taste.
• A feeling of dizziness or ‘spinning’, hallucinations, mood changes, unpleasant or uncomfortable mood, a feeling of extreme happiness, restlessness, agitation, generally feeling unwell, loss of memory, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness in the hands or feet, seizures, fits or convulsions, blurred vision, fainting, unusual muscle stiffness or slackness, involuntary muscle contractions.
• Difficulty passing urine, impotence, decreased sexual drive, low levels of sex hormones in the blood (‘hypogonadism’, seen in a blood test).
• Fast, irregular heartbeat, flushing of the skin.
• Dehydration, thirst, chills, swelling of the hands, ankles or feet.
• Dry skin, severe flaking or peeling of the skin.
• Redness of the face, reduction in size of the pupils in the eye, muscle spasm, high temperature.
• A need to use increasingly higher doses of this medicine to obtain the same level of pain relief (tolerance).
• Colicky abdominal pain or discomfort.
• A worsening of liver function tests (seen in a blood test)
• Drug withdrawal syndrome

Rare (May affect up to 1 in 1,000 people)
• Low blood pressure.
• A feeling of 'faintness' especially on standing up.
• Hives (nettle rash).

Not known (Frequency cannot be estimated from the available data)
• An increased sensitivity to pain.
• Aggression.
• Tooth decay.
• Absence of menstrual periods.
• A blockage in the flow of bile from the liver (cholestasis). This can cause itchy skin, yellow skin, very dark urine and very pale stools.
• Long term use of Oxycodone injection during pregnancy may cause life-threatening withdrawal symptoms in the newborn. Symptoms to look for in the baby include irritability, hyperactivity and abnormal sleep pattern, high pitched cry, shaking, being sick, diarrhoea and not putting on weight.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below.

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail:medsafety@hpra.ie

Malta
ADR Reporting
www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oxycodone Injection

Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special temperature storage conditions.
- Keep the ampoules in the outer carton in order to protect from light.
- Do not use after the expiry date (shown as Exp. on the packaging). The expiry date refers to the last day of the month, your doctor or nurse will check for this.
- This medicine should be used immediately after opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Oxycodone Injection contains
The active ingredient is oxycodone hydrochloride. Each ml contains oxycodone hydrochloride 10mg (equivalent to 9mg oxycodone base).

Each 1 ml ampoule contains oxycodone hydrochloride 10 mg (equivalent to 9 mg of oxycodone base). Each 2 ml contains oxycodone hydrochloride 20 mg (equivalent to 18mg of oxycodone base).

The other ingredients are: citric acid monohydrate, sodium citrate, sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.

What Oxycodone Injection looks like and the contents of the pack
Oxycodone Injection is a clear colourless solution and is supplied in packs of 5 containing either 1ml or 2ml clear glass ampoules.

Marketing Authorisation Holder: Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

This medicinal product is authorised in the Member States of the EEA under the following names:
Ireland: Oxycodone Hydrochloride 10mg/ml Solution for Injection or Infusion
Cyprus: Oxycodone Wockhardt 10mg/ml ενέσιμο διάλυμα ή διάλυμα για έγχυση
Malta: Oxycodone Hydrochloride 10mg/ml Solution for Injection or Infusion
Poland: Oxycodone Polpharma, 10 mg/ml, roztwór do wstrzykiwań lub infuzji

This leaflet was last revised in 12/2020.

Information for Healthcare Professionals

Oxycodone Hydrochloride10 mg/ml Solution for Injection or Infusion.

Please refer to the Summary of Product Characteristics (SmPC) for further details on this product.

Qualitative and Quantitative Composition
Each ml contains oxycodone hydrochloride 10 mg (equivalent to 9 mg of oxycodone base).
Each 1 ml ampoule contains oxycodone hydrochloride 10 mg (equivalent to 9 mg of oxycodone base).
Each 2 ml contains oxycodone hydrochloride 20 mg (equivalent to 18mg of oxycodone base).

This medicinal product contains less than 1 mmol sodium (23 mg) per <dose>.

For full list of excipients, refer to “Pharmaceutical Particulars”.

Pharmaceutical Form
Solution for injection or infusion (injection or infusion).
A clear, colourless solution practically free of particles.

Therapeutic indications
For the treatment of moderate to severe pain in patients with cancer and post-operative pain. For the treatment of severe pain requiring the use of a strong opioid.

Posology and method of administration
Route of administration:
Subcutaneous injection or infusion.
Intravenous injection or infusion.

Posology:
The dose should be adjusted according to the severity of pain, the total condition of the patient and previous or concurrent medication.

Adults over 18 years:
The following starting doses are recommended. A gradual increase in dose may be required if analgesia is inadequate or if pain severity increases.

i.v. (Bolus): Dilute to 1 mg/ml in 0.9% saline, 5% dextrose or water for injections. Administer a bolus dose of 1 to 10 mg slowly over one to two minutes.

Doses should not be administered more frequently than every four hours.

i.v. (Infusion): Dilute to 1 mg/ml in 0.9% saline, 5% dextrose or water for injections. A starting dose of 2 mg/hour is recommended.

i.v. (PCA): Dilute to 1 mg/ml in 0.9% saline, 5% dextrose or water for injections. Bolus doses of 0.03 mg/kg should be administered with a minimum lock-out time of five minutes.

s.c. (Bolus): Use as 10 mg/ml concentration. A starting dose of 5 mg is recommended, repeated at four-hourly intervals as required.

s.c. (Infusion): Dilute in 0.9% saline, 5% dextrose or water for injections if required. A starting dose of 7.5 mg/day is recommended in opioid naïve patients, titrating gradually according to symptom control. Cancer patients transferring from oral oxycodone may require much higher doses (see below).

Transferring patients between oral and parenteral oxycodone:
The dose should be based on the following ratio: 2 mg of oral oxycodone is equivalent to 1 mg of parenteral oxycodone. It must be emphasised that this is a guide to the dose required. Inter-patient variability requires that each patient is carefully titrated to the appropriate dose.

Elderly:
Elderly patients should be treated with caution. The lowest dose should be administered with careful titration to pain control.

Patients with renal and hepatic impairment:

Patients with mild to moderate renal impairment and/or mild hepatic impairment should be treated with caution. The lowest dose should be given with careful titration to pain control.

Children under 18 years:
There are no data on the use of Oxycodone injection in patients under 18 years of age.

Use in non-malignant pain:
Opioids are not first-line therapy for chronic non-malignant pain, nor are they recommended as the only treatment. Types of chronic pain which have been shown to be alleviated by strong opioids include chronic osteoarthritic pain and intervertebral disc disease. The need for continued treatment in non-malignant pain should be assessed at regular intervals.

Cessation of therapy:
When a patient no longer requires therapy with oxycodone, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.

Pharmaceutical Particulars
Excipients
Citric acid monohydrate, sodium citrate, sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment),
water for injections.

Incompatibilities
This medicinal product must not be mixed with other medicinal products except those mentioned under "Special precautions for disposal and other handling".

Cyclizine at concentrations of 3 mg/ml or less, when mixed with Oxycodone injection, either undiluted or diluted with water for injections, shows no sign of precipitation over a period of 24 hours storage at room temperature. Precipitation has been shown to occur in mixtures with Oxycodone injection at cyclizine concentrations greater than 3 mg/ml or when diluted with 0.9% saline. It is recommended that water for injections be used as a diluent when cyclizine and oxycodone hydrochloride are co-administered either intravenously or subcutaneously as an infusion. Prochlorperazine is chemically incompatible with Oxycodone injection.

Shelf life
Unopened: 2 years.
The injection should be given immediately after opening the ampoule. Once opened, any unused portion should be discarded. Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution, dilution, etc has taken place in controlled and validated aseptic conditions.

Special precautions for storage
This medicinal product does not require any special temperature storage conditions.
Keep the ampoules in the outer carton in order to protect from light.

Nature and contents of container
Type I clear glass ampoules: 1 ml and 2 ml.
Pack size: 5 ampoules.

Special precautions for disposal and other handling

Oxycodone injection has been shown to be compatible with the following drugs:

Hyoscine butylbromide
Hyoscine hydrobromide
Dexamethasone sodium phosphate
Haloperidol
Midazolam hydrochloride
Metoclopramide hydrochloride
Levomepromazine hydrochloride

Oxycodone injection, undiluted or diluted to 1 mg/ml with 0.9% w/v saline, 5% w/v dextrose or water for injections, is physically and chemically stable when in contact with representative brands of polypropylene or polycarbonate syringes, polyethylene or PVC tubing, and PVC or EVA infusion bags, over a 24 hour period at room temperature.

The injection, whether undiluted or diluted to 1 mg/ml in the infusion fluids used in these studies and contained in the various assemblies, does not need to be protected from light.

Inappropriate handling of the undiluted solution after opening of the original ampoule, or of the diluted solutions may compromise the sterility of the product.

Marketing Authorisation Holder

Pinewood Laboratories Ltd.
Ballymacarbry
Clonmel
Co. Tipperary
Ireland

Marketing Authorisation Number
PA 0281_235_001
MA 143/04301 *(10mg in 1ml)*
MA 143/04302 *(20mg in 2ml)*

9. Date of First Authorisation/Renewal of the Authorisation
Ireland: 16/07/2010
Malta: 22/07/2010

Date of Revision of the Text

12/2020