

Package leaflet: Information for the user

Oxycodone Hydrochloride 50 mg/ml
Solution for Injection or Infusion

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, ask your doctor, pharmacist or nurse.
- 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.

The name of your medicine is Oxycodone Hydrochloride 50 mg/ml Solution for Injection or Infusion. In the rest of this leaflet it is called Oxycodone Injection.

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'. The other ingredients are listed in section 6 of this leaflet.

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;
- are under 18 years of age.

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 take 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 taking this medicine.

Other medicines and Oxycodone Injection

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines. If you use Oxycodone Injection with some other medicines, the effect of Oxycodone Injection or the

other medicines may be changed. 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 tranquillisers, hypnotics or sedatives);
- 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.

Oxycodone Injection with food, drink and alcohol

Drinking alcohol during your treatment with Oxycodone 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 taking Oxycodone injection.

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

Pregnancy and breast-feeding

Do not use Oxycodone Injection if you are pregnant or breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before using this medicine.

Driving and using machines

You may feel sleepy when you first start using Oxycodone Injection, or when increasing 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 taking 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 taking this medicine.

Oxycodone Injection contains sodium

This injection contains less than 1 mmol sodium (23 mg) per 1 ml, i.e. it is 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.

The recommended starting dose for adults over 18 years old 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 usual 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 usual 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.



Information for Healthcare Professionals

Oxycodone Hydrochloride 50 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 50 mg (equivalent to 45 mg of oxycodone base). This medicinal product contains less than 1 mmol sodium (23 mg) per dose.

For the full list of excipients, see Section 6.1.

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 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 in opioid naive patients. Doses should not be administered more frequently than every four hours.

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

i.v. (PCA): Dilute 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 for opioid naive patients.

s.c. (Bolus): Dilute in 0.9% saline, 5% dextrose or water for injections. A starting dose of 5 mg is recommended, repeated at four-hourly intervals as required for opioid naive patients.

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 naive 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.

Use in children

Children and adolescents under 18 years of age should not be given the injection.

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, pharmacist or nurse if you are unsure.

If you find that you are still in pain whilst being given Oxycodone 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 and sick. 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.

If you have any further questions on the use of Oxycodone 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 Oxycodone Injection.

Other 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 taking 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 heart beat, 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 take 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)

Rare: may affect up to 1 in 1,000 people

- Low blood pressure.
- A feeling of 'faintness' especially on standing up.
- Hives (nettle rash).

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) and water for injections.

Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned below (special precautions for disposal/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, as cyclizine will precipitate in the presence of 0.9% saline.

Prochlorperazine is chemically incompatible with Oxycodone injection.

Shelf life and special precautions for storage/handling

Unopened: 24 months.

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.

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, or 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:

United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

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

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. Accidental overdose by a child is dangerous and may be fatal.

Do not use Oxycodone Injection after the expiry date which is stated on the ampoule label and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the ampoule in the outer carton in order to protect from light. 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.

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 to protect the environment.

6. Contents of the pack and other information

What Oxycodone Injection contains

The active ingredient is oxycodone hydrochloride. The other ingredients are: Citric acid monohydrate, sodium citrate, sodium chloride, hydrochloric acid (dilute), sodium hydroxide (dilute) and water for injections.

What Oxycodone Injection looks like and contents of the pack

Oxycodone Injection is a clear, colourless solution practically free of particles supplied in clear glass ampoules. The 50 mg/ml strength is available as 1 ml of solution, containing 50 mg of oxycodone hydrochloride (equivalent to 45mg of oxycodone base). It is available in packs of 5 ampoules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer

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

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information:

Product name	Reference number
Oxycodone Hydrochloride 50 mg/ml Solution for Injection or Infusion	PL 29831/0367

This is a service provided by the Royal National Institute of Blind People.

For patients in the Republic of Ireland, please call UK +44 1978 669272.

This medicinal product is authorised in the Member States of the EEA under the following names:

UK and Ireland: Oxycodone Hydrochloride 50 mg/ml Solution for Injection or Infusion.

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Do not store above 25°C. Keep the ampoule in the outer carton in order to protect from light.

Nature and contents of container

Type I neutral glass ampoules: 1 ml. Pack size: 5 ampoules.

Special precautions for disposal

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

Hyoscine butylbromide
Hyoscine hydrobromide
Dexamethasone sodium phosphate
Haloperidol
Midazolam hydrochloride
Metoclopramide hydrochloride
Levomethopromazine 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.

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Marketing Authorisation Holder

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Marketing Authorisation Number

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