Package leaflet: Information for the user

Oxycodone Hydrochloride 50mg/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 50mg/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

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 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
- you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction")
- are a smoker
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses
- have an increased sensitivity to pain
- need to take increasingly higher doses of Oxycodone to gain the same level of pain relief (tolerance).

Tolerance, dependence and addiction

This medicine contains oxycodone which is an opioid medicine. Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as tolerance).

Repeated use of Oxycodone Injection may lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it. You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Oxycodone Injection if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction")
- You are a smoker
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Oxycodone Injection, it could be a sign that you have become dependent or addicted.

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop using Oxycodone Injection).

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

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

Sleep-related breathing disorders

Oxycodone injection can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Other medicines and Oxycodone Injection

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.

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.

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.

Please tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines, including those obtained without a prescription. 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 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.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

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

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.

Pregnancy

You should not use this injection during pregnancy and labour unless you have been specifically told by your doctor. Depending on the dose and duration of therapy with oxycodone, slow and shallow breathing (respiratory depression) or withdrawal symptoms may occur in the newborn infant.

Breast-feeding

This injection should not be used while breast-feeding because the active ingredient may pass into breast milk.

Driving and using machines

This injection may cause a number of side effects such as drowsiness or dizziness which could affect your ability to drive or use machinery (see section 4 'Possible side effects' for a full

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Information for Healthcare Professionals

Oxycodone Hydrochloride 50mg/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 50mg (equivalent to 45mg of oxycodone base).

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 1mg/ml in 0.9% saline, 5% dextrose or water for injections. Administer a bolus dose of 1 to 10mg 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 to 1mg/ml in 0.9% saline, 5% dextrose or water for injections. A starting dose of 2mg/hour is recommended for opioid naive patients.

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

s.c. (Bolus): Use as 10mg/ml concentration. 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 to 1mg/ml 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: 2mg of oral oxycodone is equivalent to 1mg 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.

Conversion from morphine

Patients switching from parenteral morphine to parenteral oxycodone therapy should do so on the basis of a one to one dose ratio. It must be emphasised that this is a guide to the dose of Oxycodone injection 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:

The dose initiation should follow a conservative approach in these patients. The recommended adult starting dose should be reduced by 50% (for example a total daily dose of 10mg orally in opioid naïve patients), and each patient should be titrated to adequate pain control according to their clinical situation.

Children under 18 years:

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

list of side effects). These are usually most noticeable when you first start using the injection, or when increasing to a higher dose. If you are affected you should not drive or use machinery.

- Do not drive whilst taking this medicine until you know how this medicine affects you.
- It is an offence to drive while you have this medicine in your body over a specified limit unless you have a defence (called the 'statutory defence').
- This defence applies when:
  - The medicine has been prescribed to treat a medical or dental problem; and
  - You have taken it according to the instructions given by the prescriber and in the information provided with the medicine.
- Please note that it is still an offence to drive if you are unfit because of the medicine (i.e. your ability to drive is being affected).

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: https://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 1mmol sodium (23mg) per 1ml, 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.
Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Oxycodone Injection, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also If you stop using Oxycodone Injection).

Adults (over 18 years of age)
The usual starting dose is dependent upon how the injection is administered. The usual starting doses are as follows:

- As a single injection into a vein, the usual dose is 1 to 10mg given slowly over 1 to 2 minutes. This can be repeated every 4 hours.
- As an infusion into a vein, the usual starting dose is 2mg/hour.
- As a single injection through a fine needle into the tissue under the skin, the usual starting dose is 5mg 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 7.5mg/day.
- If given by patient controlled analgesia (PCA), the dose is worked out according to your weight (0.03mg per kg of body weight). Your doctor or nurse will set a suitable frequency.

Children
Children and adolescents under 18 years of age should not be given this 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. An overdose may result in a brain disorder (known as toxic leukoencephalopathy).
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
Do not suddenly stop using this injection. 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 that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.
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)
- Drug withdrawal syndrome
- Dependence.

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
- Sleep apnoea (breathing pauses during sleep)
- a problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction).

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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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. Store this medicine in a locked safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.
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 50mg/ml strength is available as 1ml of solution, containing 50mg 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 50mg/ml Solution for Injection or Infusion	29831/0367

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

This medicinal product is authorised in the Member States of the EEA under the following names:
UK and Ireland: Oxycodone Hydrochloride 50mg/ml Solution for Injection or Infusion.

This leaflet was last revised in 01/2024.

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WOCKHARDT

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.

Treatment goals and discontinuation
Before initiating treatment with Oxycodone Injection, a treatment strategy including treatment duration and treatment goals, and a plan for end of the treatment, should be agreed together with the patient, in accordance with pain management guidelines. During treatment, there should be frequent contact between the physician and the patient to evaluate the need for continued treatment, consider discontinuation and to adjust dosages if needed. When a patient no longer requires therapy with oxycodone, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal. In absence of adequate pain control, the possibility of hyperalgesia, tolerance and progression of underlying disease should be considered (see section 4.4).

Duration of treatment
Oxycodone should not be used for longer than necessary.

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 3mg/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 3mg/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.
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: 1ml. 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 • Levomepromazine hydrochloride
Oxycodone injection, undiluted or diluted to 1mg/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.

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