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

This injection has been prescribed for you by your doctor to relieve moderate to severe pain. It contains the active ingredient oxycodone which is a strong analgesic (‘painkiller’) which belongs to a group of medicines called opioids. 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) or have previously had an allergic reaction when taking other strong analgesics or painkillers (such as morphine or other opioids);
• have breathing problems, such as severe chronic obstructive lung disease, severe bronchial asthma or severe respiratory depression. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
• have a condition where the bowel does not work properly (paralytic ileus) or you have severe pain in your abdomen (acute abdomen);
• have a heart problem after long-term lung disease (cor pulmonale);
• have increased carbon dioxide levels in the blood. Symptoms may include dizziness, drowsiness, fatigue, shortness of breath and headache.

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);
• have myxoedema (a thyroid disorder with dryness, coldness and swelling or 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 following use of certain medicines (toxic psychosis);
• have inflammation of the pancreas (which causes severe pain in the abdomen and back) or problems with your gall bladder or bile duct;
• have a blockage of the gut or an inflammatory bowel disorder;
• have colicky abdominal pain or discomfort;
• 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;
• 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 withdrawal symptoms such as agitation, anxiety, palpitations, shaking or sweating upon stopping taking alcohol or drugs;
• suffer from seizures, fits or convulsions;
• are feeling light-headed or faint;
• have an increased sensitivity to pain;
• suffer from constipation
• have a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea;
• are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks.

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.

If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital that you have been given this injection.

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

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. Long-term use of this medicine can lead to a need to take increasingly higher doses to gain the same level of pain relief (tolerance). If you stop using this medicine suddenly you may experience withdrawal syndrome (see ‘If you stop using Oxycodone Injection’ below).

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).

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
Using Oxycodone Injection at the same time as other medicines that slow down the central nervous system can cause slow or difficulty breathing (respiratory depression), severe sleepiness, loss of consciousness and death. These medicines include:
• other medicines used to treat pain known as opioids (such as codeine or morphine);
• medicines used to treat epilepsy (gabapentinoids) such as pregabalin;
• medicines used to treat anxiety;
• medicines used to make you feel sleepy (such as benzodiazepines);
• medicines used to treat psychiatric or mental disorders (such as phenothiazines);
• anaesthetics;
• muscle relaxants;
• medicines used to treat high blood pressure;
• medicines used to treat depression, including a type of medicine known as monoamine oxidase inhibitors (MAOIs), such as tranylcypromine, phenelzine and isocarboxazid. You may be affected if you have taken these medicines in the last two weeks.

Because of this, your doctor will only prescribe Oxycodone Injection where there are no other treatment options, and only in small doses for short periods of time. If you or your friends, family or caregivers notice that you are having difficulty breathing or that you have become very sleepy or lost consciousness you (or they) should inform your doctor immediately.

Concomitant use of Oxycodone Injection and sedative medicines such as benzodiazepines or related drugs 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 Oxycodone Injection with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Using Oxycodone Injection with medicines used to treat depression known as Selective Serotonin Re-uptake Inhibitors (SSRIs) or Selective Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) can cause a condition known as serotonin toxicity. The symptoms of this include agitation, seeing or hearing things that aren't real (hallucinations), loss of consciousness, a fast heartbeat, blood pressure changes, increased body temperature, muscle twitching, lack of coordination, stiffness, feeling or being sick, or diarrhoea. If you are taking SSRI or SNRI medicines such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline and venlafaxine your doctor may reduce your dose of Oxycodone Injection.

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.

Tell your doctor or pharmacist if you are taking any of the following medicines, as they may need to adjust your dose:
• a type of medicine used to treat depression known as tricyclic antidepressants, such as amitriptyline, clomipramine, imipramine, lofepramine or nortriptyline;
• medicines used to treat allergies, such as cetirizine, fexofenadine or chlorphenamine;
• quinidine (a medicine to treat a fast heartbeat);
• cimetidine, a medicine used to treat stomach ulcers;
• antifungal medicines such as ketoconazole, voriconazole, itraconazole and posaconazole;
• antibiotics such as clarithromycin, erythromycin or telithromycin;
• medicines used to treat HIV known as protease inhibitors, such as boceprevir, ritonavir, indinavir, nelfinavir or saquinavir;
• rifampicin, a medicine used to treat tuberculosis;
• medicines used to treat seizures, fits or convulsions such as carbamazepine and phenytoin;
• a herbal remedy used to treat depression known as St. John's Wort (also known as *Hypericum perforatum*);
• medicines used 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
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 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.
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.

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 10 mg 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 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.

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 you an alternative medicine or 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. An overdose may result in:
• a reduction in size of pupils in the eye
• breathing more slowly or weakly than expected (respiratory depression)
• drowsiness or loss of consciousness
• low muscle tone (hypotonia)
• reduced pulse rate
• a fall in blood pressure
• difficulty in breathing due to fluid on the lungs (pulmonary oedema)
• a brain disorder (known as toxic leukoencephalopathy)

In severe cases an overdose may lead to unconsciousness or even death. When seeking medical attention make sure that you take this leaflet and any remaining injection with you to show to the doctor.

If you have been given too much or too high a dose of the injection under no circumstances should you put yourself in a situation that requires you to be alert e.g. driving a car.

If you stop using Oxycodone Injection
Do 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 withdrawal effects. Withdrawal symptoms such as yawning, abnormal dilation of the pupil of the eye, tear disorder, runny nose, agitation, anxiety, convulsions, difficulty in sleeping, palpitations, shaking 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) and can lead to severe sleepiness and loss of consciousness. This side effect may affect up to 1 in 100 people and is more likely to occur when takin certain other medicines (see section 2 'Other medicines and Oxycodone Injection'). **Tell your doctor immediately** if this happens to you. You may wish to ask your friends, family or caregivers to monitor you for these signs and symptoms.

As with all strong analgesics or painkillers, there is a risk that you may become addicted to or dependent on Oxycodone Injection. You may also find you need a higher dose to gain the same level of pain relief (tolerance). These side effects may affect up to 1 in 100 people.

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.
• Difficulty in passing urine.
• Rash, sweating, high temperature.

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 or unpleasant taste, mouth ulcers, sore mouth.
• A condition which causes abnormal production of antidiuretic hormone (syndrome of inappropriate antidiuretic hormone secretion).
• A feeling of dizziness or spinning (vertigo), hallucinations, mood swings, a feeling of extreme happiness, agitation, generally feeling unwell, loss of memory, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness, seizures, fits or convulsions, abnormal manner or style of walking, feeling detached from oneself, being unusually overactive, fainting, reduced consciousness, unusual muscle stiffness or slackness, involuntary muscle contractions.
• Impotence, decreased sexual drive, low levels of sex hormones in the blood ('hypogonadism', seen in a blood test).
• Flushing of the skin.
• Dehydration, weight change, thirst, swelling of the hands, ankles or feet.
• Dry skin.
• Tear disorder, blurred or impaired vision, reduction in size of the pupils in the eye.
• A ringing or buzzing sound in the ears.
• Swelling and irritation inside the nose, nose bleeds, voice alteration.
• Chills.
• Chest pain.
• Inability to fully empty the bladder.
• A worsening of liver function tests (seen in a blood test).
• Withdrawal symptoms (see section 3 'If you stop using Oxycodone Injection'.

Rare: may affect up to 1 in 1,000 people
• Low blood pressure or feeling faint, especially on standing up.
• A raised itchy rash (hives).

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).
• Colicky abdominal pain or discomfort.
• 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 national reporting systems listed below:

Ireland:
HPRA Pharmacovigilance. Website: www.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. 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. 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 45 mg of oxycodone base). It is available in packs of 5 ampoules.

Marketing Authorisation Holder and Manufacturer

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

This leaflet was last revised in 01/2024.

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).

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:
Prescribers should consider concomitant treatment with antiemetics and laxatives for the prevention of nausea, vomiting and constipation.

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 in opioid naive patients. 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 for opioid naive patients.

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 for opioid naive patients.

s.c. (Bolus): Use as 10 mg/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 1 mg/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: 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.

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:
The lowest dose should be administered with careful titration to pain control. Controlled pharmacokinetic studies in elderly patients (aged over 65 years) have shown that compared with younger adults the clearance of oxycodone is only slightly reduced. No untoward adverse drug reactions were seen based on age, therefore adult doses and dosage intervals are appropriate.

Patients with renal or 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 10 mg orally in opioid naïve patients), and each patient should be titrated to adequate pain control according to their clinical situation.

Unlike morphine preparations, the administration of oxycodone does not result in significant levels of active metabolites. However, the plasma concentration of oxycodone in this patient population may be increased compared with patients having normal renal or hepatic function.

Studies involving other intravenous oxycodone preparations, administered by bolus injection to six patients with end-stage liver cirrhosis and ten patients with end-stage renal failure have been reported in the literature. In each case, the elimination of oxycodone was impaired.

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.

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 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.

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 • 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.

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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