Package leaflet: Information for the user

Oxycodone Hydrochloride 10 mg/ml solution for injection or infusion
oxycodone hydrochloride

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 or pharmacist.
- 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 10 mg/ml solution for injection or infusion, which will be referred to as Oxycodone Injection throughout this leaflet.

What is in this leaflet

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

This medicine 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 to oxycodone, or any of the other ingredients of this medicine (listed in section 6);
- if you 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;
- if you have a condition where the small bowel does not work properly (paralytic ileus) or you have severe pain in your abdomen;
- if you have a heart problem after long-term lung disease (cor pulmonale);
- if you have ongoing problems with constipation;
- if you 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 of Oxycodone Injection;

- 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 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 Injection to gain the same level of pain relief (tolerance).

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

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

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose 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, have recently taken or might take any other medicines, including medicines obtained without a prescription. If you use this injection with some other medicines, the effect of this 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; llmedicines 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 heart beat);
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn);
- medicines to treat fungal infections (such as ketoconazole, voriconazole, itraconazole and posaconazole);
- medicines used to treat infections (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 to 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.

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 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 are 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 or pharmacist for advice before taking this medicine.

Pregnancy
The medicine is not recommended for use 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 be observed in the newborn.

Breast-feeding
The medicine should not be used in breast-feeding mothers because oxycodone may be secreted in breast milk and may cause respiratory depression in the newborn.

Driving and using machines
You may feel sleepy when you first start using this medicine, 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 as it may make you sleepy or dizzy.
- Do not drive while taking this medicine until you know how it affects you.

- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
    - 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 or in the information provided with the medicine and
    - It was not affecting your ability to drive safely

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 medicine contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially 'sodium-free'.

3. How to use Oxycodone Injection

Your doctor will decide the correct dosage for you and how and when the medicine will be given. The dose and how often this medicine is given may be adjusted according to the severity of your pain. The medicine can be administered as an injection or infusion under your skin (subcutaneous injection) or directly into a vein (intravenous injection). Your nurse or doctor will give you the medicine.

Use in children and adolescents
Children and adolescents under 18 years of age should not be given this medicine.

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 Oxycodone Injection discuss this with your doctor.

If you use more Oxycodone Injection than you should, or if someone else uses your medicine
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 medicine with you to show to the doctor.

If you stop using Oxycodone Injection
You should not suddenly stop using this medicine unless your doctor tells you to. If you want to stop using your medicine, 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 medicine.

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

4. Possible side effects

Like all medicines, this medicine 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.

Very common side effects
(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 side effects
(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 side effects
(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 side effects
(May affect up to 1 in 1,000 people)
- Low blood pressure.
- A feeling of "faintness" especially on standing up.
- Hives (nettle rash).

Frequency 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie.

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. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.
Keep the ampoule in the outer carton in order to protect from light.
Once the ampoule is opened the medicine should be used immediately. Any unused portion should be discarded immediately.

The medicine should be examined visually and should not be used if particulate matter or discolouration are present.

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 substance is oxycodone hydrochloride.

The other ingredients are:
- Citric acid monohydrate
- Sodium citrate dihydrate
- Sodium chloride
- Hydrochloric acid
- Sodium hydroxide
- Water for injections

What Oxycodone Injection looks like and contents of the pack
Oxycodone Injection is a clear colourless solution, practically free from visible particles supplied in colourless glass ampoules.
Each 1 ml ampoule contains 10 mg oxycodone hydrochloride (equivalent to 9 mg oxycodone).
Each 2 ml ampoule contains 20 mg oxycodone hydrochloride (equivalent to 18 mg oxycodone).

Pack size: 5, 10 ampoules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

hameln pharma plus gmbh
Langes Feld 13
31789 Hameln, Germany

Manufacturer

HBM Pharma s.r.o.
Sklabinská 30
03680 Martin, Slovakia

hameln rds a.s.
Horná 36
900 01 Modra, Slovakia

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

AT	Oxycodon-hameln 10 mg/ml Injektions-/Infusionslösung
DE	Oxycodon-hameln 10 mg/ml Injektions-/Infusionslösung
DK	Oxycodone Hameln
IE	Oxycodone Hydrochloride 10 mg/ml solution for injection or infusion
NO	Oxycodone Hameln
PL	Oxycodone Hydrochloride Hameln
SE	Oxycodone Hameln 10 mg/ml injektions-/infusionsvätska, lösning
UK	Oxycodone Hydrochloride 10 mg/ml solution for injection or infusion

Distributor

hameln pharmaceuticals ltd
Gloucester, United Kingdom

For any information about this medicine, please contact the Distributor.

This leaflet was last revised in 03/2019.

The following information is intended for healthcare professionals only:

PREPARATION GUIDE:

Oxycodone Hydrochloride 10 mg/ml solution for injection or infusion

Please refer to the Summary of Product Characteristics for full prescribing and other information.

Therapeutic indications

Oxycodone is indicated in adults 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.

Administration

For intravenous or subcutaneous use.

Dilution

Each ampoule is for single use in a single patient. This medicine should be given immediately after opening the ampoule and any unused portion should be discarded.

The medicinal product should be examined visually and should not be used if particulate matter or discolouration are present.

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 25°C.

The 10 mg/ml injection, whether undiluted or diluted to 1 mg/ml in the infusion fluids and containers detailed above, does not need to be protected from light over a 24 hour period.

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

The following information is intended for healthcare professionals only:

(*Continued from overleaf*)

Oxycodone Hydrochloride 10 mg/ml solution for injection or infusion

Compatibilities

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

Incompatibilities

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 25°C. 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 ampoules: 30 months.

Opened ampoules: The product should be used immediately after opening the ampoule.

Prepared infusion solutions:
Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.
For instructions on dilution of the medicinal product before administration, see the section on **Dilution** overleaf.
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 dilution has taken place in controlled and validated aseptic conditions.