Package leaflet: Information for the user

***OxyNorm*® 50 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, 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.

What is in this leaflet:

1. What *OxyNorm* injection is and what it is used for

OxyNorm injection is a strong analgesic painkiller and belongs to the group of opioids.
OxyNorm injection is used in adults and adolescents from 12 years and older for the relief of severe pain, which can be adequately managed only with opioid analgesics.

2. What you need to know before you use *OxyNorm* injection

Do not use *OxyNorm* injection if you:
- are allergic (hypersensitive) to oxycodone or any of the other ingredients of the injection (listed in section 6 of this leaflet) 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 and weakly than expected;
- have a head injury that causes a severe headache or makes you feel sick. This is because the injection may make these symptoms worse or hide the extent of the head injury;
- have a condition where the bowel does not work properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying) or you have severe sudden 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 this injection if you:
- are elderly or weakened;
- have an under-active thyroid gland (hypothyroidism);
- have myxoedema (a thyroid disorder associated with dryness, coldness, and swelling or puffiness of the skin, affecting the face and limbs);
- know you are suffering from a brain injury or tumour, have a 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 may cause 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) for example Addison's disease;
- have breathing problems such as severely impaired pulmonary function, chronic obstructive airways disease, severe lung disease or reduced respiratory reserve. 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 increase in 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.

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.

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.

<u>Tolerance, dependence and addiction</u>
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 ***OxyNorm*** injection can also 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 ***OxyNorm*** injection' in section 3 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 ***OxyNorm*** 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 ***OxyNorm*** 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 taking ***OxyNorm*** injection)

Sleep-related breathing disorders
OxyNorm 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 *OxyNorm* injection
Using ***OxyNorm*** 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 ***OxyNorm*** 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 ***OxyNorm*** 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 ***OxyNorm*** 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 the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Using ***OxyNorm*** 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 ***OxyNorm*** injection.

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines 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;
- medicines used to treat Parkinson's disease;
- antibiotics such as clarithromycin, erythromycin or telithromycin;
- antifungal medicines such as ketoconazole, voriconazole, itraconazole and posaconazole;
- medicines used to treat HIV known as protease inhibitors, such as boceprevir, ritonavir, indinavir, nelfinavir or saquinavir;
- cimetidine, a medicine used to treat stomach ulcers;
- 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*);
- quinidine, a medicine used to treat an irregular heartbeat.

Using *OxyNorm* injection with food, drink and alcohol
Drinking alcohol during your treatment with this injection may make you feel more 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 that you do not drink alcohol while you are using ***OxyNorm*** injection.

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

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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.

Breastfeeding
This injection should not be used while breastfeeding 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.

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

3. How to use *OxyNorm* injection

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using ***OxyNorm*** 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 taking ***OxyNorm*** injection).

Your doctor will adjust your dosage according to pain intensity and to your individual needs. A doctor or nurse will usually prepare and administer the injection for you.

Children below 12 years of age
Safety and efficacy of ***OxyNorm*** injection have not been tested sufficiently in children under 12 years of age. Therefore, treatment with ***OxyNorm*** injection is not recommended in children under 12 years of age.

Method of administration
A doctor or nurse will usually administer ***OxyNorm*** injection for you.

OxyNorm injection is intended for infusion after dilution into a vein (intravenous = IV) or through a fine needle under the skin (subcutaneous = SC).

For intravenous use ***OxyNorm*** injection is to be diluted to a concentration 1 mg/ml oxycodone hydrochloride. The following solutions for infusion/injection can be used as diluent 0.9% w/v sodium chloride solution, 5% w/v glucose solution or water for injections.

For subcutaneous use, if necessary, ***OxyNorm*** injection can be diluted with the following solutions for infusion/injection 0.9% w/v sodium chloride solution, 5% w/v glucose solution or water for injections.

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 upon your condition.

If you use more *OxyNorm* injection than you should, or if someone else uses your injection
Call your doctor or hospital **immediately**. 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 *OxyNorm* injection
You should not suddenly stop using this injection unless your doctor tells you to. If you want to stop using your injection, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects. Withdrawal symptoms such as 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 using this injection.

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 injection can cause side effects, although not everybody gets them.

This medicine can cause allergic reactions, although serious allergic reactions are reported in rare cases. **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. These may be signs of a serious allergic reaction.

The most serious side effect is a condition where you breathe more slowly or weakly than usual (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 taking certain other medicines (see section 2 'Other medicines and ***OxyNorm*** 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 these tablets. 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.

Very common: may affect more than 1 in 10 people
- constipation (your doctor can prescribe a laxative to overcome this problem);
- feeling or being sick (this should normally wear off after a few days however your doctor can prescribe an anti-sickness medicine if it continues to be a problem);
- drowsiness (this is most likely when you start using your injection 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;
- wheezing or difficulty in breathing, 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 in liver function tests (seen in a blood test);
- withdrawal symptoms (see section 3 'If you stop using ***OxyNorm*** 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
- sleep apnoea (breathing pauses during sleep);
- tooth decay;
- colicky abdominal pain or discomfort;
- a problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction).
- a blockage in the flow of bile from the liver. This can cause itchy skin, yellow skin, very dark urine and very pale stools;
- absence of menstrual periods;
- an increase in sensitivity to pain;
- aggression;

Long term use of ***OxyNorm*** injection during pregnancy may cause life-threatening withdrawal symptoms in the newborn. Symptoms to look for in the baby include irritability, hyperactivity and abnormal sleep pattern, high pitched cry, shaking, being sick, diarrhoea and not putting on weight.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance at: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store *OxyNorm* injection

Keep this medicine out of the sight and reach of children. Accidental overdose by a child is dangerous and may be fatal. 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 this medicine 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.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light. However, once the ampoule is opened the injection should be used immediately. Any unused portion should be discarded immediately.

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

6. Contents of the pack and other information

What *OxyNorm* injection contains

The active ingredient is oxycodone hydrochloride. Each 1 ml contains 50 mg of oxycodone hydrochloride.

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

What *OxyNorm* injection looks like and contents of the pack

The injection is a clear, colourless to pale yellow solution supplied in clear glass ampoules. The 50 mg/ml strength is available as 1 ml of solution (containing 50 mg of oxycodone hydrochloride).

The ampoules are packed in boxes. Pack size: 5 ampoules.

Marketing Authorisation Holder

Mundipharma Pharmaceuticals Limited, Millbank House, Arkle Road, Sandyford, Dublin 18, Ireland.

Manufacturer

Mundipharma DC B.V, Leusderend 16, 3832 RC Leusden, The Netherlands.

This leaflet is also available in large print, Braille or as an audio CD. To request a copy, please call the RNIB Medicine Information line on:

0044 1733 37 53 70

You will need to give details of the product name and reference number.
These are as follows:

Product name: ***OxyNorm* 50** mg/ml
Reference number: PA 1688/6/10

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