MUNDIPHARMA (PTY) LTD	
OxyNorm® Injection 10 mg, 20 mg	Oxycodone hydrochloride Solution for injection or infusion

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

OxyNorm® 10 mg Injection (Solution for Injection or Infusion)

OxyNorm® 20 mg Injection (Solution for Injection or Infusion)

Active substance(s)

Oxycodone hydrochloride

Read all of this leaflet carefully before you are administered OxyNorm® Injection

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- OxyNorm® Injection has been prescribed for you personally. Do not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What OxyNorm® Injection is and what it is used for
2. What you need to know before you are administered OxyNorm® Injection
3. Receiving OxyNorm® Injection
4. Possible side effects
5. How to store OxyNorm® Injection
6. Contents of the pack and other information

1. What OxyNorm® Injection is and what it is used for

OxyNorm® Injection is indicated for the short-term treatment of moderate to severe pain in

patients with cancer and post-operative pain.

OxyNorm® Injection is indicated for the short-term treatment of severe pain requiring the use of a strong opioid analgesic.

2. What you need to know before you are administered OxyNorm® Injection

You should not be administered OxyNorm® Injection if you:

- are allergic (hypersensitive) to oxycodone, or any of the other ingredients of OxyNorm® Injection (see section 6);
- have breathing problems, such as chronic obstructive airways disease, chronic bronchial asthma or 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 head injury that causes a severe headache or makes you feel sick. This is because OxyNorm® Injection may make these symptoms worse or hide the extent of the head injury;
- 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 severe kidney problems or moderate to severe liver problems. If you have other long-term kidney or liver problems you should only be administered this injection if recommended by your doctor;
- have ongoing problems with constipation;
- are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or have taken this type of medicine in the last two weeks;
- are pregnant;
- are under 18 years of age.

Warnings and precautions

Take special care with OxyNorm® Injection if you:

- have an under-active thyroid gland (hypothyroidism), as you may need a lower dose;
- 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 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) or problems with your gall bladder;
- have inflammatory bowel disease;
- have prostate problems;
- 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);
- 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;
- are or have ever been addicted to alcohol or drugs;
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking alcohol or drugs;
- have chronic kidney and/or liver disease;
- are more sensitive towards pain or feel that you need higher doses to control your level of pain;
- are using hormone replacement therapy or if you are prone to hormonal imbalance.

Other medicines and OxyNorm® Injection

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

If you are treated with OxyNorm® Injection at the same time as some other medicines, the effect of OxyNorm® Injection or the other medicine may be changed.

The risk of side effects is increased if you are treated with OxyNorm® Injection at the same time as some other medicines.

This injection must not be used together with a monoamine oxidase inhibitor, or if you have taken this type of medicine in the last two weeks (see section 2 above).

Tell your doctor or pharmacist if you are taking:

- medicines to help you sleep (for example tranquillisers, hypnotics or sedatives) especially medicines called benzodiazepines;
- medicines to treat depression;
- medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptics);
- other strong analgesics or 'painkillers';
- muscle relaxants;
- medicines to treat high blood pressure;
- medicines with anticholinergic actions (such as antihistamines, antipsychotics and anti-Parkinson medicines);
- antibiotics, anti-fungal treatment, anti-viral treatment;
- medicine to treat tuberculosis (rifampicin);
- St. John's Wort;
- frequent grapefruit juice;
- anti-convulsion medicine such as phenytoin, carbamazepine;
- medicine to treat heart rhythm, such as quinidine.

Also tell your doctor if you have recently been given an anaesthetic.

Using OxyNorm® Injection with antidepressants that increase the amount of Serotonin in the brain, known as Selective Serotonin Re-uptake Inhibitor (SSRI) or a Serotonin Norepinephrine Re-uptake Inhibitor (SNRI) may cause serotonin toxicity. Symptoms can include agitation, hallucinations, faster heartbeat, sudden changes in blood pressure, high body temperature, over active reflexes, incoordination, muscle stiffness, nausea, vomiting, or diarrhoea.

OxyNorm® Injection with food and drink

Drinking alcohol during your treatment with OxyNorm® Injection may make you sleepy. If you are affected you should avoid drinking alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Do not use this injection if you are pregnant or breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

If used over prolonged periods during pregnancy, oxycodone may lead to withdrawal symptoms in the newborn baby. If oxycodone is given during childbirth, the baby may have breathing problems (respiratory depression).

Breastfeeding should be discontinued during treatment with this injection. Oxycodone passes into breast milk.

Driving and using machines

OxyNorm® Injection may cause a number of side effects such as drowsiness which could affect your ability to drive or use machinery (see section 4 for a full list of side effects).

These are usually most noticeable when you first start using OxyNorm® Injection, or when changing to a higher dose. If you are affected you should not drive or use machinery.

OxyNorm® Injection contains:

The active substance is oxycodone.

Each OxyNorm® 10 mg Injection contains 10 mg/1 ml of oxycodone hydrochloride equivalent to 9 mg/1 ml oxycodone.

Each OxyNorm® 20 mg Injection contains 20 mg/2 ml of oxycodone hydrochloride equivalent to 18 mg/2 ml oxycodone.

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

3. Receiving OxyNorm® Injection

You will not be expected to give yourself OxyNorm® Injection, it will be given by a person who is qualified to do so.

Your doctor will tell you how long your treatment will last and how often OxyNorm® Injection will be administered. Your doctor may adjust your dose according to the severity of your pain.

If you have the impression that the effect of OxyNorm® Injection is too strong or too weak, talk to your doctor or pharmacist.

Adults (over 18 years of age): Since a healthcare professional will administer OxyNorm® Injection, he/she will control the dosage.

Children: Children and adolescents under 18 years of age should not be given OxyNorm® Injection.

If you are given more OxyNorm Injection® than you should be given

Since a healthcare professional will administer OxyNorm® Injection, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdosage. If you have received an overdose you may feel very sleepy, sick (nausea, vomiting) or dizzy. You may also have breathing difficulties leading to unconsciousness or even death and may need emergency treatment in hospital.

If you forget to administer a dose of OxyNorm® Injection

Since a healthcare professional will administer OxyNorm® Injection, he/she will control the dosage**.**

If you stop taking OxyNorm® Injection®

If you want to stop using OxyNorm® Injection, discuss this with your doctor first. He/She 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 injection.

If you have any further questions on how OxyNorm® Injection should be used, ask your doctor or pharmacist.

4. Possible side effects

OxyNorm® Injection can have side effects.

Not all side efects reported for OxyNorm® Injection are included in this leaflet. Should your general health worsen while being treated with OxyNorm® Injection, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- any sudden wheeziness,

- difficulties in breathing (respiratory depression),
- swelling of the eyelids, face or lips,
- rash or itching especially those covering your whole body.

These are very serious side effects. If you have them you may have had a serious allergic reaction to OxyNorm® Injection.

Tell your doctor or go to the casualty department at your nearest hospital if you notice any of the following:

- A feeling of dizziness 'spinning', a feeling of 'faintness' especially on standing up, confusion (disorientation), imagining things (hallucinations), mood changes, depression, a feeling of extreme happiness, restlessness, agitation, generally feeling unwell, loss of memory, shaking, difficulties with speech, reduced sensitivity to pain or touch, tingling in the hands or feet, seizures, fits or convulsions, blurred vision.
- Fast, irregular heart-beat, low blood pressure, flushing of the skin.
- Redness of the face, reduction in size of the pupils in the eye, muscle spasm, abnormal increase in muscle tension (rigidity), high temperature.
- Dry skin, severe flaking or peeling of the skin.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Constipation (your doctor may prescribe a laxative to overcome this problem).
- Dry mouth, loss of appetite, indigestion, abdominal pain or discomfort, diarrhoea.
- Headache, confusion, a feeling of unusual weakness, dizziness, anxiety, nervousness, twitching, difficulty in sleeping, abnormal thoughts or dreams.
- Sweating, weakness.

Less frequent side effects:

- Difficulty in swallowing, belching, hiccups, wind, gastrointestinal disorder (e.g. upset stomach), changes in taste.
- Difficulty passing urine, impotence, decreased sexual drive, absence of menstrual periods.
- Dehydration, thirst, swelling of the hands, ankles or feet.
- A need to take increasingly higher doses to obtain the same level of pain relief (tolerance).
- Withdrawal symptoms (such as agitation, anxiety, palpitations, shaking, or sweating).
- Feel angrier than usual or get angry easily.
- Experience pain easier than usual.
- Teeth cavities.
- Decreased gall bladder function.
- Chills.
- Withdrawal symptoms in the newborn.
- Sleep apnoea syndrome (abnormal breathing while sleeping).

The following side effects may occur at the beginning of treatment, but normally wear off after a few days:

- Feeling or being sick (your doctor can prescribe an anti-sickness medicine if it continues to be a problem).
- Drowsiness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of OxyNorm® Injection.

Alternatively report to: ZADrugSafety@mundipharma.co.za

5. How to store OxyNorm® Injection

- Store all medicines out of reach of children.
- Store at or below 25 °C in original package in the outer carton.
- Do not use this injection after the expiry date which is stated on the ampoule label and carton.
- Once the ampoule is opened, the injection should be used immediately and may only be used once. Any unused portion should be discarded immediately.
- Do not refrigerate or freeze.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

6. Contents of the pack and other information

What OxyNorm® Injection contains

The active substance is oxycodone hydrochloride.

Each OxyNorm® 10 mg Injection contains 10 mg/1 ml of oxycodone hydrochloride equivalent to 9 mg/1 ml oxycodone.

Each OxyNorm® 20 mg Injection contains 20 mg/2 ml of oxycodone hydrochloride equivalent to 18 mg/2 ml oxycodone.

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

What OxyNorm® Injection looks like and contents of the pack

OxyNorm® 10 mg Injection: Clear, colourless solution, practically free from particulates.

OxyNorm® 20 mg Injection: Clear, colourless solution, practically free from particulates.

OxyNorm® 10 mg Injection: 1 ml Type 1 Ph.Eur clear glass ampoules with white break ring and yellow identification ring in cardboard boxes of 5 ampoules per box.

OxyNorm® 20 mg Injection: 2 ml Type 1 Ph.Eur clear glass ampoules with white break ring and red identification ring in cardboard boxes of 5 ampoules per box.

Holder of Certificate of Registration

Mundipharma (Pty) Ltd

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South Africa

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OxyNorm® 10 mg Injection: 46/2.9/0718

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Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.

® = OxyNorm is a registered trademark