MUNDIPHARMA (PTY) LTD	
OxyContin® Prolonged Release Tablets 5 mg, 10 mg, 20 mg, 40 mg, 80 mg	Oxycodone hydrochloride Prolonged release tablets

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

OxyContin® 5 mg Prolonged Release Tablets

OxyContin® 10 mg Prolonged Release Tablets

OxyContin® 20 mg Prolonged Release Tablets

OxyContin® 40 mg Prolonged Release Tablets

OxyContin® 80 mg Prolonged Release Tablets

Oxycodone hydrochloride

Contains sugar. This product contains lactose monohydrate.

This medicine contains oxycodone which is an opioid, that can cause addiction. You can get withdrawal symptoms if your stop taking it suddenly.

Read all of this leaflet carefully before you start taking OxyContin®

- 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.
- OxyContin® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist.

What is in this leaflet

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

1. What OxyContin® is and what it is used for

OxyContin® is a strong analgesic or "painkiller" and belongs to the group of opioids.

OxyContin® is used for the relief of moderate to severe pain in patients with cancer and post-operative pain, after gastrointestinal function has returned.

OxyContin® is used for the relief of severe pain requiring the use of a strong opioid analgesic.

2. What you need to know before you take OxyContin®

Do not take OxyContin®:

- if you are allergic (hypersensitive) to the active ingredient oxycodone hydrochloride or any of the other ingredients (see "What OxyContin® contains");
- if you suffer from severe breathing problems, especially if there is a lowered supply of oxygen to the blood (hypoxia) and/or increased carbon dioxide saturation of the blood (hypercapnia);
- if you suffer from obstructive lung disease;
- if you have a heart problem after long-term lung disease (cor pulmonale);
- if you suffer from bronchial asthma; short term or long term;
- where the small bowel does not work properly (paralytic ileus);

- during pregnancy and breast-feeding;
- in the presence of severe lung-, liver- or kidney diseases;
- if you are taking a type of medicine known as a monoamine oxidase inhibitor or if you have taken this type of medicine in the last two weeks;
- in any situation where opioids are contraindicated;
- if you suffer from a head injury that causes a severe headache or makes you feel sick;
- if you suffer from severe pain in your abdomen;
- if your stomach empties more slowly than it should (delayed gastric emptying);
- if you suffer from on-going constipation (hard, infrequent stools);
- pre-operatively or for the first 12 - 24 hours after an operation;
- if you suffer from rare hereditary problems of galactose intolerance, e.g. Galactosaemia, the Lapp lactase deficiency or glucose-galactose malabsorption;
- if you are under the age of 18 years.

Warnings and precautions

Take special care with OxyContin®:

- with elderly or weakened patients;
- if anyone in your family are or have ever been addicted to opioids, alcohol, prescription medicines or illegal drugs;
- if you have an under-active thyroid (hypothyroidism), as you may need a lower dose of OxyContin®;
- if you have poor adrenal gland function (Addison's disease);
- if you have prostate problems;
- if you have a mental disorder as a result of an infection (toxic psychosis);
- if you are or ever have been addicted to alcohol or drugs;

- if you have previously suffered from withdrawal symptoms such as agitation, anxiety; shaking or sweating, upon stopping taking alcohol or drugs;
- if you have inflammation of the pancreas (pancreatitis) or problems with your gall bladder;
- if you have a severe headache, have a head injury or feel sick as this may indicate that the pressure in your skull is increased;
- if you have decreased kidney or liver function;
- if you have any difficulty breathing;
- if you are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxacid, moclobemide and linezolid) (see “Other medicines and OxyContin®”);
- if you have had abdominal (stomach) surgery;
- if you have difficulty swallowing or have gastrointestinal disorders, such as oesophageal cancer or colon cancer;
- if you have low blood pressure (hypotension) or low blood volume (hypovolemia),
- if you have inflammatory bowel disease.

Tolerance, dependence and addiction

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

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 OxyContin® 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 OxyContin®, 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 OxyContin®).

OxyContin® can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxaemia (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.

In order to avoid weakening the prolonged release effect of the tablets, the prolonged release tablets should not be pre-soaked, licked or otherwise made wet prior to placing in the mouth and must be taken one tablet at a time with enough water to ensure complete

swallowing immediately after placing in the mouth. **Tablets must be swallowed whole and are not allowed to be broken, chewed or crushed. Taking broken, chewed or crushed tablets leads to speedier release of the active ingredient and to the absorption of a potentially fatal dose of the active ingredient oxycodone** (see "If you take more OxyContin® than you should").

You may see residue of the tablet in your stool. Do not worry, as the active ingredient oxycodone has been released earlier while the tablet passed through the gastric system and has started to be effective in your body.
Increased sensitivity to pain that does not respond to dose increase can develop. If this happens, your doctor will reduce your dose or switch you to an alternative opioid painkiller.

OxyContin® 80 mg should not be taken by patients, who have not taken opioids before, as their potency may lead to a life-threatening respiratory depression in this group of patients. Long term use of OxyContin® may require continual dose increases to achieve the desired pain relief. Long term use of OxyContin® may lead to physical dependence and a withdrawal syndrome may occur when treatment is stopped suddenly. When you no longer require treatment with OxyContin®, you may require gradual decrease of the dose to prevent symptoms of withdrawal. Babies born to dependent mothers may exhibit withdrawal symptoms and may have breathing difficulty at birth (see "Pregnancy and breastfeeding").

Children and adolescents

OxyContin® has not been tested in children and adolescents under 18 years of age. Therefore, safety and efficacy are not established and OxyContin® is not recommended in children and adolescents under 18 years of age.

Elderly persons

In elderly patients without liver and/or kidney disease, a dose adjustment is usually unnecessary.

Other medicines and OxyContin®

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

If you take OxyContin® with some other medicines, the effect of OxyContin® or the other medicine may be changed.

OxyContin® must not be used together with a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid) (see “Take special care with OxyContin®”), or if you have taken this type of medicine in the last two weeks.

Using OxyContin® 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.

Tell your doctor or pharmacist:

- if you are taking medicines to help you sleep (for example tranquillisers, hypnotics or sedatives);
- if you have recently been given an anaesthetic;
- if you are taking medicines to treat depression;
- if you are taking medicines to treat psychiatric or mental disorders;
- if you are taking other strong analgesics or ‘painkillers’;
- if you are taking muscle relaxants;

- if you are taking medicines to treat high blood pressure;
- if you are taking quinidine (a medicine to treat a fast heartbeat);
- if you are taking cimetidine (a medicine for stomach ulcers, indigestion or heartburn);
- if you are taking antifungal medicines (such as ketoconazole);
- if you are taking antibiotics (such as erythromycin);
- if you are taking medicine to treat HIV (such as ritonavir);
- if you are taking medicine to treat tuberculosis (such as rifampicin);
- if you are taking medicine to treat epilepsy (such as carbamazepine or phenytoin)

Grapefruit juice may also increase the blood levels of oxycodone and should not be drunk whilst taking OxyContin®.

OxyContin® with food and drink

You can take OxyContin® with or without food.

Drinking alcohol during your treatment with OxyContin® 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 health care provider for advice before taking this medicine. (see “Do not take OxyContin®”).

Do not take OxyContin® during pregnancy.

The active ingredient, oxycodone, is transported through the placenta. The long-term use of OxyContin® during pregnancy may lead to withdrawal symptoms in newborn infants. If taken during birth, breathing problems may occur in the child.

Do not take OxyContin® during periods of breast-feeding, since the active substance oxycodone may pass into the breast milk.

Driving and using machines

You may feel sleepy or dizzy when you first start taking OxyContin®, or when changing to a higher dose. If you are affected, you should not drive or use machinery.

It is not always possible to predict to what extent OxyContin® may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which OxyContin® affects them.

OxyContin® contains:

Tablet core: ammoniomethacrylate co-polymer, lactose monohydrate, magnesium stearate, povidone, stearyl alcohol, talc, triacetin.

Tablet coat: hypromellose, macrogol, talc, titanium dioxide.

OxyContin® 5 mg contains Brilliant blue FCF aluminium lake.

OxyContin® 10 mg contains hydroxypropylcellulose and no additional colourant.

OxyContin® 20 mg contains polysorbate and iron oxide red.

OxyContin® 40 mg contains polysorbate and iron oxide yellow.

OxyContin® 80 mg contains hydroxypropylcellulose, iron oxide yellow and indigo carmine.

Contains sugar. This product contains lactose monohydrate.

OxyContin® contains lactose. If you have been told by your doctor that you have an intolerance to some sugars. Contact your doctor before taking OxyContin®.

Patients with the rare hereditary condition of galactose intolerance e.g. galactosaemia or glucose-galactose malabsorption should not take OxyContin®.

3. How to take OxyContin®

Do not share medicines prescribed for you with any other person.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using OxyContin®.

Always take OxyContin® exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

Adults (over 18 years of age)

Your doctor will tell you how long your treatment with OxyContin® will last. Do not stop your treatment earlier. If you have the impression that the effect of OxyContin® is too strong or too weak, tell your doctor or pharmacist.

Unless otherwise prescribed by your doctor, the usual dose for adults older than 18 years old is one prolonged release tablet of OxyContin® 10 mg (10 mg oxycodone hydrochloride) at 12-hour intervals. Some patients may benefit from a starting dose of 5 mg to minimise the side effects.

Swallow the prolonged release tablets without chewing, breaking or crushing and with sufficient liquid (half a glass of water) in the morning and evening in accordance to a fixed time schedule (e.g. in the morning at 8 a.m., in the evening at 8 p.m.). You can take OxyContin® with or without food.

OxyContin® is for oral use only (swallowing tablets whole). Improper injection (injection into a blood vessel) of the dissolved tablets must not be done, because this may lead to serious side effects which may be fatal.

Some patients receiving OxyContin® on a fixed time schedule require immediate-release painkillers for fast relief from breakthrough pain. OxyContin® is not intended for the treatment of breakthrough pain.

Elderly patients

In elderly patients without kidney and/or liver disease, dosage adjustment is usually not necessary.

Liver or kidney impairment

Patients with mild to moderate kidney and/or liver disease who have not received opioids before should initially take half of the recommended adult dose. This also applies to patients with low body weight and patients who metabolise medications at slower rates.

Children under 18 years

OxyContin® has not been tested in children and adolescents under 18 years of age. Therefore, safety and efficacy are not established (see "Take special care with OxyContin®").

If you take more OxyContin® than you should

In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison centre.

People who have taken an overdose may feel very sleepy and sick or dizzy or have hallucinations. Overdose may result in a brain disorder (known as toxic leukoencephalopathy). 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 tablets with you to show to the doctor.

If you forget to take OxyContin®

Do not take a double dose to make up for a forgotten individual dose.

If you take a smaller dose of OxyContin® than prescribed, or if you have completely forgotten to take your dose, this will lead to unsatisfactory and/or insufficient pain relief.

If you have forgotten to take your dose once, you may take it later only if the next regular dose was scheduled more than 8 hours later. You may then continue to follow your usual schedule. If the time to the next dose is shorter than 8 hours, take the prolonged-release tablets, but postpone the next dose by 8 hours. As a matter of principle, you should never take OxyContin® more frequently than at 8-hourly intervals.

If you stop taking OxyContin®

Do not stop taking OxyContin® suddenly without telling your doctor.

If you want to stop taking your tablets, discuss this with your doctor first, who will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant withdrawal effects.

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

4. Possible side effects

OxyContin® can have side effects.

Not all side efects reported for OxyContin® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OxyContin®, please consult your health care provider for advice.

All medicines can cause allergic reactions, including serious allergic reactions. 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).

There is a risk that you may become addicted or reliant on OxyContin®.

Frequent side effects

- Most people will have constipation when they take OxyContin®. Your doctor can prescribe a laxative to overcome this problem;
- You may feel sick or vomit (be sick) when you take these prolonged release tablets. Your doctor can prescribe an anti-vomiting medicine if it continues to be a problem;
- You may find that you feel more sleepy than normal when you start taking your tablets or when your dose is increased;

- Dry mouth, loss of appetite, indigestion, abdominal pain or discomfort, diarrhoea; hiccups;
- Headache, confusion, a feeling of unusual weakness, dizziness, anxiety, nervousness, twitching, difficulty in sleeping, abnormal thoughts or dreams; depression, uncontrollable shaking (tremor), mood or personality changes, feeling less active, restlessness;
- Frequent or painful urination;
- Difficulty in breathing or wheezing, shortness of breath;
- Rash, itchy skin;
- Sweating.

Less frequent side effects

- Hypersensitivity reactions;
- Inflamed mouth, oral ulcers, gum bleeding;
- Difficulty in swallowing, belching, wind, retching (feeling of wanting to vomit), indigestion, changes in taste; intestinal obstruction, abnormal dark tarry faeces containing blood, dental problems;
- Increased liver enzymes; abdominal pain related to the gallbladder due to gallstones;
- Increased appetite;
- Decrease in concentration, migraine;
- A feeling of dizziness or ‘spinning’, a feeling of ‘faintness’ especially on standing up, hallucinations, feeling strange (derealisation), a feeling of extreme happiness, agitation, generally feeling unwell and emotional, loss of memory, difficulties with speech, reduced sensitivity to pain or touch, tingling or numbness, seizures, fits or convulsions, medicine dependence, chills;
- Decreased muscle tone, involuntary muscle spasm, changes in coordination;

- Herpes simplex (disorder of the skin and mucosa);
- Difficulty in passing urine;
- Reduced levels of sex hormones, impotence, decreased sexual drive,
- Fast or irregular heartbeat, low blood pressure, flushing of the skin;
- Increased coughing, voice changes;
- Injuries due to accidents;
- Choking, medicine stuck in throat;
- Pain (e.g. chest pain);
- Dehydration, thirst, swelling of the hands, ankles or feet;
- Changes in body weight (loss or gain);
- Dry skin, hives (red itchy rash);
- Vision impairment (having sight problems), reduction in size of the pupils in the eye;
- A need to take increasingly higher doses of OxyContin® to gain the same level of pain relief (tolerance);
- Withdrawal symptoms such as restlessness, teary eyes, running nose, yawning, chills, muscle pain, increase in the size of the eye pupils, agitation, anxiety, backache, joint pain, weakness, stomach cramps, sleeplessness, nausea, weight loss, vomiting, diarrhoea, increased blood pressure, increased respiratory (breathing) rate, increased heart rate or sweating upon stopping taking OxyContin®.

Side effects of which the frequency is unknown

- Tooth decay;
- Problems with bile flow;
- Increased sensitivity to pain which cannot be improved by increasing the dose;
- Aggression;
- Acute generalized allergic reactions (anaphylactic and anaphylactoid reactions);
- 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;
- Withdrawal symptoms in newborn infants;
- Sleep apnoea syndrome (a sleep disorder in which breathing repeatedly stops and starts).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of OxyContin®.

Alternatively report to the following e-mail address: ZADrugsafety@mundipharma.co.za.

5. How to store OxyContin®

- Store all medicines out of 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.
- Store at or below 25 °C. Store in original package in the outer carton in order to protect from light.
- Do not use OxyContin® after the expiry date which is stated on the blister and carton after “Expiry date”. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OxyContin® contains

The active substance is oxycodone hydrochloride.

Each OxyContin® 5 mg Prolonged Release Tablet contains 5 mg oxycodone hydrochloride.

Each OxyContin® 10 mg Prolonged Release Tablet contains 10 mg oxycodone hydrochloride.

Each OxyContin® 20 mg Prolonged Release Tablet contains 20 mg oxycodone hydrochloride.

Each OxyContin® 40 mg Prolonged Release Tablet contains 40 mg oxycodone hydrochloride.

Each OxyContin® 80 mg Prolonged Release Tablet contains 80 mg oxycodone hydrochloride.

The other ingredients are:

Tablet core: ammoniomethacrylate co-polymer, lactose monohydrate, magnesium stearate, povidone, stearyl alcohol, talc, triacetin.

Tablet coat: hypromellose, macrogol, talc, titanium dioxide.

OxyContin® 5 mg contains Brilliant blue FCF aluminium lake.

OxyContin® 10 mg contains hydroxypropylcellulose and no additional colourant.

OxyContin® 20 mg contains polysorbate and iron oxide red.

OxyContin® 40 mg contains polysorbate and iron oxide yellow.

OxyContin® 80 mg contains hydroxypropylcellulose, iron oxide yellow and indigo carmine.

Contains sugar. This product contains lactose monohydrate.

What OxyContin® looks like and contents of the pack

OxyContin® 5 mg Prolonged Release Tablets are pale blue, round, bi-convex, film coated tablets, imprinted with OC on one side and 5 on the other side.

OxyContin® 10 mg Prolonged Release Tablets are white, round, bi-convex, film coated tablets, imprinted with OC on one side and 10 on the other side.

OxyContin® 20 mg Prolonged Release Tablets are pink, round, bi-convex, film coated tablets, imprinted with OC on one side and 20 on the other side.

OxyContin® 40 mg Prolonged Release Tablets are yellow, round, bi-convex, film coated tablets, imprinted with OC on one side and 40 on the other side.

OxyContin® 80 mg Prolonged Release Tablets are green, round, bi-convex, film coated tablet, imprinted with OC on one side and 80 on the other side.

All strengths of OxyContin® Prolonged Release Tablets are supplied in clear PVC and aluminium foil blister packs of 28.

Holder of Certificate of Registration

Mundipharma (Pty) Ltd

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South Africa

This leaflet was last revised on

12 February 2026

Registration numbers

South Africa: S6

OxyContin® 5 mg Prolonged Release Tablets: 41/2.9/1098

OxyContin® 10 mg Prolonged Release Tablets: 41/2.9/1099

OxyContin® 20 mg Prolonged Release Tablets: 41/2.9/1100

OxyContin® 40 mg Prolonged Release Tablets: 41/2.9/1101

OxyContin® 80 mg Prolonged Release Tablets: 41/2.9/1102

Namibia: NS4

OxyContin® 5 mg Prolonged Release Tablets: 12/2.9/0259

OxyContin® 10 mg Prolonged Release Tablets: 12/2.9/0260

OxyContin® 20 mg Prolonged Release Tablets: 12/2.9/0261

OxyContin® 40 mg Prolonged Release Tablets: 12/2.9/0262

OxyContin® 80 mg Prolonged Release Tablets: 12/2.9/0263

Botswana: S1A

OxyContin® 5 mg Prolonged Release Tablets: BOT1402343

OxyContin® 10 mg Prolonged Release Tablets: BOT1402344

OxyContin® 20 mg Prolonged Release Tablets: BOT1402345

OxyContin® 40 mg Prolonged Release Tablets: BOT1402346

OxyContin® 80 mg Prolonged Release Tablets: BOT1402347

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.

® = OxyContin is a registered trademark.