

Approved Patient Information Leaflet for Medicines for Human Use:

OXYCORRELL ONCE DAILY

SCHEDULING STATUS: S6

Oxycorrell 10 mg /20 mg /40 mg and 80 mg Once Daily

Prolonged Release Tablets

Oxycodone hydrochloride

Contains sugar (sucrose)

Each Oxycorrell 10 mg Once Daily tablet contains 5 mg sucrose.

Each Oxycorrell 20 mg Once Daily tablet contains 10 mg sucrose.

Each Oxycorrell 40 mg Once Daily tablet contains 20 mg sucrose.

Each Oxycorrell 80 mg Once Daily 80 mg tablet contains 40 mg sucrose.

Read all of this leaflet carefully before you start taking Oxycorrell Once Daily

- 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.
- Oxycorrell Once Daily 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.

What is in this leaflet

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

1. What Oxycorrell Once Daily is and what it is used for

Oxycorrell Once Daily contain the active ingredient oxycodone which belongs to a group of medicines called opioids which are strong analgesics or 'painkillers'.

Oxycorrell Once Daily is used to treat severe pain over a period of 24 hours, which can be adequately managed only with opioid analgesics.

Oxycorrell Once Daily is indicated in adults over 18 years.

2. What you need to know before you take Oxycorrell Once Daily

Do not take Oxycorrell Once Daily

- if you are hypersensitive (allergic) to oxycodone hydrochloride or any of the other ingredients of Oxycorrell Once Daily (listed in section 6)
- if you have breathing problems, such as severe chronic obstructive lung disease, severe bronchial asthma or severely depressed breathing (respiratory depression) with too little oxygen in the blood (hypoxia) and/or too much carbon dioxide (hypercarbia) in the blood. Your doctor would 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 gastrointestinal problems, such as a condition where the small bowel does not work properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying), you have severe pain in your abdomen (acute abdomen) or suffer from ongoing problems with constipation
- if you have a heart problem after long-term lung disease (cor pulmonale)
- if you have moderate to severe liver problems. If you have other long-term liver problems you should only take these tablets if recommended by your doctor
- if you are under 18 years of age.

Warnings and precautions

Tell your doctor or health care provider before being given Oxycorrell Once Daily if you

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- are elderly or weakened
- have an under-active thyroid gland (hypothyroidism), as you may need a lower dose
- 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 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
- 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 Oxycorrell Once Daily to gain the same level of pain relief (tolerance)
- are taking a type of medicine known as a monoamine oxidase inhibitor (MAOI) or you have taken this type of medicine in the last two weeks (see Other medicines and Oxycorrell Once Daily)

Surgery

If you are going to have an operation, please tell the doctor at the hospital that you are taking these tablets.

Long-term treatment and abuse

Oxycorrell Once Daily has primary dependence potential. This means that, when Oxycorrell Once Daily is used for a long time a diminished effect may occur at the dose you usually receive, and progressively higher doses may be required to maintain pain control.

Chronic use of Oxycorrell Once Daily may lead to physical dependence and a withdrawal syndrome may occur upon abrupt cessation. During withdrawal syndrome you can experience the several unpleasant side effects (see section 3, “If you stop taking Oxycorrell Once Daily”). When you no longer require therapy with oxycodone hydrochloride, it is advisable to taper the dose gradually to prevent symptoms of withdrawal. Your doctor will instruct you how to taper the dose when necessary.

When Oxycorrell Once Daily is correctly used as directed by your doctor for severe chronic pain, the risk of developing physical or psychological dependence is markedly reduced. Please discuss this with your doctor if you are concerned.

Addiction

There is an increased risk of addiction in patients with a personal or family history of substance abuse or mental health disorders.

Oxycorrell Once Daily tablets should be used with particular care in patients with a history of alcohol and substance abuse.

Incorrect use of Oxycorrell Once Daily

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The prolonged release tablet must be swallowed whole, not be chewed or crushed as this leads to rapid oxycodone release due to the damage of the prolonged release properties. The administration of chewed or crushed Oxycorrell Once Daily leads to a rapid release and absorption of a potentially fatal dose of oxycodone (see section 3 “If you take more Oxycorrell Once Daily than you should”).

In case of abusive injection (injection in a vein) the other tablet ingredients may lead to destruction and death (necrosis) of the local tissue, change of lung tissue (granulomas of the lung) or other serious, potentially lethal events.

Alcohol

You should not take alcohol while you are taking Oxycorrell Once Daily as the undesirable effects of Oxycorrell Once Daily can be increased (see section 2 Other medicines and Oxycorrell Once Daily).

Anti-doping warning

If you are an athlete, you should be aware that Oxycorrell Once Daily may cause a positive reaction to “anti-doping tests”. Use of Oxycorrell Once Daily as a doping agent may become a health hazard.

Hormonal changes

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

Children and adolescents

Children and adolescents under 18 years of age should not take Oxycorrell Once Daily.

Other medicines and Oxycorrell Once Daily

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

Tell your doctor if you are taking any medicines that suppress the activity of the brain as the simultaneous use with Oxycorrell Once Daily increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening, e.g.

- medicines to help you sleep or stay calm (for example hypnotics or sedatives, including benzodiazepines)
- medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptic medicines)
- medicines used during surgery (anaesthetics)
- medicines used to treat depression (anti-depressants)
- medicines used for muscle spasms (muscle relaxants)
- medicines to treat high blood pressure
- other strong opioids analgesics ('painkillers') or alcohol can enhance the side effects of oxycodone, in particular depressed breathing (respiratory depression) which can be fatal.

Because of the increased the risk of drowsiness, difficulties in breathing (respiratory depression) and coma which may be life-threatening when opioids and medicines that suppress the activity of the brain, such as benzodiazepines are used concomitantly, it could be helpful to inform friends or relatives to be aware of these sign and symptoms. Please follow your doctor's dosage recommendation closely. Contact your doctor when experiencing such symptoms.

The risk of side effects due to too much serotonin, a chemical in the brain, increases, if you use Oxycorrell Once Daily together with anti-depressants (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 health care provider if you are taking:

- a type of medicine known as a monoamine oxidase inhibitor (MAOI) or you have taken this type of medicine in the last two weeks. MAOIs can enhance the side effects of oxycodone (e.g. excitation, decrease or increase in blood pressure)
- antihistamines (used to treat allergies)
- medicines to treat Parkinson's disease
- anticoagulants of the coumarin type (medicines against blood clotting). In individuals a clinically relevant increase or decrease of blood clotting have been observed if these type of anticoagulants are taken with Oxycorrell Once Daily tablets
- antibiotics (such as clarithromycin, erythromycin or telithromycin)
- antifungal medicines (such as ketoconazole, voriconazole, itraconazole and posaconazole)
- medicines known as 'protease inhibitors' to treat HIV (e.g. boceprevir, ritonavir, indinavir, nelfinavir or saquinavir)
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn)
- grapefruit juice
- 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*)
- quinidine (a medicine to treat a fast heart beat)

Oxycorrell Once Daily with food, drink and alcohol

Oxycorrell Once Daily can be taken with or without food.

Drinking alcohol whilst taking Oxycorrell Once Daily tablets 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

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consciousness which can be fatal. It is recommended not to drink alcohol while you're taking Oxycorrell Once Daily tablets.

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

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.

Do not take these tablets if you are pregnant or breastfeeding.

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

Driving and using machines

Oxycorrell Once Daily tablets causes a number of side effects that impair mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and / or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment to such an extent that the ability to drive and operate machinery is affected or ceases altogether.

It is not always possible to predict to what extent Oxycorrell Once Daily tablets may interfere with your daily activities therefore, you should not engage in the above activities until you are aware of the measure to which Oxycorrell Once Daily tablets affects you.

Oxycorrell Once Daily contains sucrose

This medicine contains sucrose, a sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take Oxycorrell Once Daily.

3. How to take Oxycorrell Once Daily

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

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Always take Oxycorrell Once Daily exactly as your doctor has instructed you. Check with your doctor if you are not sure.

Adults (over 18 years of age)

The usual dose of Oxycorrell Once Daily is one tablet daily. Your doctor will prescribe the exact daily dose required to treat your pain. If you find that you are still in pain whilst taking these tablets, discuss this with your doctor. Take the tablets once daily as advised by your doctor.

Your doctor will decide how to control your treatment and will regularly review it with regard to pain relief and other effects in order to achieve the best pain therapy possible for you as well as to be able to treat the side effects and to decide whether treatment should be continued.

Your doctor will adjust the dosage depending on the pain intensity and how you respond to the treatment.

Method of administration

Oxycorrell Once Daily tablets are for oral use only.

Swallow the tablets whole with a sufficient amount of liquid (half a glass of water) with or without food, preferably at the same time each day.

The tablets must be swallowed whole, not chewed, crushed or dissolved. Oxycorrell Once Daily tablets are designed to work properly over 24 hours when swallowed whole. If a tablet is crushed, dissolved or chewed, the entire 24-hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an over-dose, which may be fatal (see also section 2, “Warnings and precautions”).

You must only take the tablets by mouth. The tablets should never be crushed or injected as this may lead to serious side effects, which may be fatal (see section 2, “Warnings and precautions”).

Opening instruction for the blister

This medicinal product is packed in a child-resistant blister. You cannot press out the prolonged release tablets through the blister. Please observe the following opening instruction for the blister:

1. Tear off a single dose along the perforation line of the blister.
2. Hereby an unsealed area is accessible which is located at the position, where the perforation lines have crossed.
3. Pull at the unsealed "strap" to peel off the cover seal.

Duration of administration

Your doctor will tell you how long your treatment with Oxycorrell Once Daily will last. Do not stop treatment without informing your doctor (see "If you stop taking Oxycorrell Once Daily"). If you have the impression that the effect of Oxycorrell Once Daily is too strong or too weak, tell your doctor or pharmacist.

Children and adolescents

Children and adolescents under 18 years of age should not take the tablets.

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.

If you take more Oxycorrell Once Daily than you should

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

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The following symptoms may occur: constricted pupils (miosis), depressed breathing (respiratory depression), sleepiness, skeletal muscle flaccidity, drop in blood pressure and hallucinations (seeing and hearing things that are not really there). In severe cases circulatory collapse (failure in blood circulation in your body), drowsiness, unconsciousness (coma), slowing of the heart rate (bradycardia) and accumulation of water in the lungs (non-cardiogenic lung oedema) may occur. Abuse of high doses of strong opioids such as Oxycorrell Once Daily can be fatal. In no case should you expose yourself to situations requiring elevated concentration e.g. driving a car.

If you forget to take Oxycorrell Once Daily

If you miss the intake of Oxycorrell Once Daily, pain relief will consequently be insufficient or cease altogether.

You can make up for a forgotten dose if the next regular intake is not due for at least another 12 hours.

You can then continue to take Oxycorrell Once Daily as directed. Do not take a double dose to make up for a forgotten dose.

If you stop taking Oxycorrell Once Daily

Do not stop treatment suddenly and without informing your doctor.

A withdrawal syndrome may occur upon abrupt cessation of therapy. During withdrawal syndrome you can experience the following symptoms: restlessness, increased production of tears, runny nose, yawning, sweating, chills, muscle pain, abnormal dilatation of the pupil and sensation of irregular and forceful heartbeat. Other symptoms may also develop, including: irritability, anxiety, backache, joint pain, weakness, belly cramps, sleeplessness, being sick, lack of appetite, vomiting, diarrhoea, or increased blood pressure, breathing rate or heart rate (see also section 4 "Possible side effects").

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

4. Possible side effects

Oxycorrell Once Daily can have side effects.

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

If any of the following happens, stop taking Oxycorrell Once Daily and tell your doctor immediately or go to the casualty department at your nearest hospital:

- depressed breathing (slowed or weaker breathing). This is the most significant risk induced by opioids such as Oxycorrell Once Daily and is most likely to occur in elderly or debilitated patients. As a consequence, in predisposed patients opioids can cause severe drops in blood pressure, coma and death.
- constricted pupils, severe bronchial spasms and spasms in smooth muscles and suppression of the cough reflex
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to Oxycorrell Once Daily. You may need urgent medical attention or hospitalisation.

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

Frequent side effects

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- confusion
- drowsiness (this is most likely when you start taking your tablets or when your dose is increased, but it should wear off after a few days), dizziness
- difficulty in breathing or wheezing, shortness of breath, decreased cough reflex
- constipation, abdominal pain

Less frequent side effects

- dehydration
- dependence (addiction) which is the physical and/or psychological need for the medicine and is likely when using the medicine becomes the focus of your life and interferes with your ability to cope without the medicine
- loss of memory (amnesia), seizures, fits or convulsions, unusual muscle stiffness or slackness (hypertonia and hypotonia), involuntary muscle contractions, fainting (syncope)
- blurred vision
- a feeling of dizziness or 'spinning' (vertigo)
- fast, irregular heart beat (palpitations)
- a condition where the bowel does not work properly (ileus) inflammation of the lining of the stomach (gastritis)
- a worsening of liver function tests (seen in a blood test), colicky abdominal pain or discomfort
- severe flaking or peeling of the skin (exfoliative dermatitis) or a rash of round, red welts on the skin that itch intensely, sometimes with dangerous swelling (also called nettle rash, hives or urticaria)
- difficulty in passing urine
- impotence, decreased sexual drive, low levels of sex hormones in the blood ('hypogonadism', seen in a blood test)
- medicine withdrawal syndrome with some or all of the following symptoms: restlessness, increased production of tears, runny nose, yawning, sweating, chills, muscle pain, abnormal dilatation of the pupil, sensation of irregular and forceful heartbeat, irritability, anxiety, backache, joint pain, weakness,

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belly cramps, sleeplessness, being sick, lack of appetite, vomiting, diarrhoea, or increased blood pressure, breathing rate or heart rate

- a need to take increasingly higher doses of the tablets to obtain the same level of pain relief (tolerance)

Side effects with frequency unknown

- an increased sensitivity to pain (hyperalgesia)
- 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 Oxycorrell Once Daily 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

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- decreased appetite
- anxiety, depression, difficulty in sleeping, nervousness, abnormal thoughts or dreams
- headache
- lack of energy, shaking, a feeling of unusual weakness, tiredness
- 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)
- dry mouth, indigestion, diarrhoea

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- itchy skin, rash and sweating

Less frequent side effects

- agitation, feeling of extreme happiness, hallucinations, disorientation, mood changes, unpleasant or uncomfortable mood, a restlessness, generally feeling unwell
- difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness ('pins and needles')
- flushing of the skin and face, low blood pressure, a feeling of 'faintness' especially on standing up
- difficulty in swallowing, belching, hiccups, wind, changes in taste
- dry skin
- dehydration, thirst, chills, high body temperature, swelling of the hands, ankles or feet

Tolerance and dependence may develop with chronic use and a withdrawal syndrome may occur upon abrupt cessation of therapy. The withdrawal syndrome is characterised by some or all of the following: restlessness, increased production of tears, runny nose, yawning, sweating, chills, muscle pain, abnormal dilatation of the pupil and sensation of irregular and forceful heartbeat. Other symptoms may also develop, including: irritability, anxiety, backache, joint pain, weakness, belly cramps, sleeplessness, being sick, lack of appetite, vomiting, diarrhoea, or increased blood pressure, breathing rate or heart rate.

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 Oxycorrell Once Daily.

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Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store Oxycorrell Once Daily

- Store all medicines out of reach of children.
- Store at or below 25 °C, protected from moisture and light.
- Store in the original packaging until required for use.
- Do not store your medicine in the bathroom.
- Do not use after the expiry date stated on the blister and carton.

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 Oxycorrell Once Daily contains

The active substance is oxycodone hydrochloride.

Oxycorrell 10 mg Once Daily

Each prolonged release tablet contains 10 mg oxycodone hydrochloride.

Oxycorrell 20 mg Once Daily

Each prolonged release tablet contains 20 mg oxycodone hydrochloride.

Oxycorrell 40 mg Once Daily

Each prolonged release tablet contains 40 mg oxycodone hydrochloride.

Oxycorrell 80 mg Once Daily

Each prolonged release tablet contains 80 mg oxycodone hydrochloride.

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The other ingredients are:

Tablet core

Sugar spheres (sucrose, maize starch)

Hypromellose

Talc

Ethylcellulose

Hydroxypropylcellulose

Propylene glycol

Carmellose sodium

Cellulose, microcrystalline

Magnesium stearate (Ph. Eur.)

Silica, colloidal anhydrous

Tablet coating

Oxycorrell 10 mg Once Daily prolonged release tablets

Hypromellose

Macrogol 6000

Talc

Titanium dioxide (E171)

Oxycorrell 20 mg Once Daily prolonged release tablets

Hypromellose

Macrogol 6000

Talc

Titanium dioxide (E171)

Iron oxide, yellow (E172)

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Oxycorrell 40 mg Once Daily prolonged release tablets

Hypromellose

Macrogol 6000

Talc

Titanium dioxide (E171)

Iron oxide, red (E172)

Oxycorrell 80 mg Once Daily prolonged release tablets

Hypromellose

Macrogol 6000

Talc

Titanium dioxide (E171)

What Oxycorrell Once Daily looks like and contents of the pack

Oxycorrell 10 mg Once Daily Prolonged Release Tablets

White, round, biconvex, film-coated prolonged release tablets with a diameter of 6,16 mm.

Oxycorrell 20 mg Once Daily Prolonged Release Tablets

Yellowish to yellow, oblonged, biconvex, film-coated prolonged release tablets with a diameter of 10,2 mm x 4,7 mm and with a break line on both sides. The tablet can be divided into equal doses.

Oxycorrell 40 mg Once Daily Prolonged Release Tablets

Pink, oblonged, biconvex, film-coated prolonged release tablets with a diameter of 12,3 mm x 5,8 mm and with a break line on both sides. The tablet can be divided into equal doses.

Oxycorrell 80 mg Once Daily Prolonged Release Tablets

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White, oblonged, biconvex, film coated prolonged release tablets with a diameter of 16,3 mm x 7,8 mm and with a break line on both sides.

The tablet can be divided into equal doses.

Oxycorrell Once Daily tablets are packed in child resistant perforated unit dose PVC/PE/PVDC-aluminium blisters consisting of a white opaque PVC/PE/PVDC laminated foil and an aluminium foil.

Pack sizes: 10, 14, 20, 28, 30, 50, 56, 60, 98 and 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Oxycorrell 20 mg Once Daily prolonged release tablets: 50/2.9/0942

Oxycorrell 40 mg Once Daily prolonged release tablets: 50/2.9/0943

Oxycorrell 80 mg Once Daily prolonged release tablets: 50/2.9/0944

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL: <https://austell.co.za/product-info/>

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