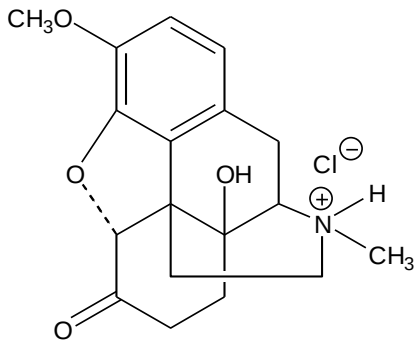
PRODUCT INFORMATION

OxyNorm® capsules (5 mg, 10 mg and 20 mg)
OxyNorm® liquid (1 mg/ mL)

NAME OF THE MEDICINE

Non-proprietary name: Oxycodone hydrochloride
Chemical name: 4,5α-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride
CAS No.: 124-90-3
Molecular formula: $C_{18}H_{21}NO_4$
Molecular weight: 351.83
Structural formula:



DESCRIPTION

Oxycodone hydrochloride is a white, crystalline odourless powder readily soluble in water, sparingly soluble in ethanol and nearly insoluble in ether.

The inactive ingredients in OxyNorm capsules are: microcrystalline cellulose and magnesium stearate.

The capsule shells and printing ink contain the following materials:

Material	5 mg capsule	10 mg capsule	20 mg capsule
Indigo carmine CI 73015 (E132)	•	•	•
Iron oxide red CI 77491 (E172)	•	•	•
Iron oxide yellow CI 77492 (E172)	•	•	•
Sunset yellow FCF CI 15985 (E110)	•		
Titanium dioxide (E171)	•	•	•
Empty Hard Gelatin Capsules 4722-1	•		
Empty Hard Gelatin Capsules 4723-1		•	
Empty Hard Gelatin Capsules 4724-1			•
OPACODE monogramming ink S-1-277002 BLACK	•	•	•

The inactive ingredients in OxyNorm liquid are: saccharin sodium, sodium benzoate, citric acid monohydrate, sodium citrate dihydrate and hypromellose.

PHARMACOLOGY

Actions

Oxycodone is a full opioid agonist with no antagonist properties whose principal therapeutic action is analgesia. It has affinity for kappa, mu and delta opiate receptors in the brain and spinal cord. Oxycodone is similar to morphine in its action. Other pharmacological actions of oxycodone are in the central nervous system (respiratory depression, antitussive, anxiolytic, sedative and miosis), smooth muscle (constipation, reduction in gastric, biliary and pancreatic secretions, spasm of sphincter of Oddi and transient elevations in serum amylase) and cardiovascular system (release of histamine and/or peripheral vasodilatation, possibly causing pruritus, flushing, red eyes, sweating and/or orthostatic hypotension).

Pharmacokinetics

Absorption

Compared with morphine, which has an absolute bioavailability of approximately 30%, oxycodone undergoes relatively low first-pass metabolism and has a high absolute bioavailability of up to 87% following oral administration. Peak plasma concentrations of oxycodone are reached approximately one hour after administration of OxyNorm capsules, and less than one hour (approximately 45 minutes) after administration of OxyNorm liquid.

No data are available on the effect of food on the absorption of OxyNorm capsules. Limited data indicate that the absorption of oxycodone from an oral solution may be significantly affected by food. An increase in mean AUC of approximately 20% and decrease in C_{max} of approximately 20% have been reported.

Metabolism and Elimination

Oxycodone has an elimination half-life of approximately three hours and is metabolised in the liver to form noroxycodone, oxymorphone, noroxymorphone, 6 α and β oxycodol and conjugated glucuronides. CYP3A4 and CYP2D6 are involved in the formation of noroxycodone and oxymorphone, respectively (see **INTERACTIONS WITH OTHER MEDICINES**). The contribution of these metabolites to the analgesic effect is insignificant.

INDICATIONS

The management of opioid-responsive moderate to severe pain.

CONTRAINDICATIONS

Hypersensitivity to opioids or to any of the constituents of OxyNorm capsules or liquid, acute respiratory depression, *cor pulmonale*, cardiac arrhythmias, acute asthma or other obstructive airways disease, paralytic ileus, suspected surgical abdomen, severe renal impairment (creatinine clearance < 10 mL/min), severe hepatic impairment (refer to Special Risk Groups), delayed gastric emptying, acute alcoholism, brain tumour, increased cerebrospinal or intracranial pressure, head injury (due to risk of raised intracranial pressure), severe CNS depression, convulsive disorders, *delirium tremens*, hypercarbia, concurrent administration of monoamine oxidase inhibitors or within 2 weeks of discontinuation of their use. Pregnancy. Not recommended for pre-operative use.

PRECAUTIONS

The major risk of opioid excess is respiratory depression, including subclinical respiratory depression. As with all opioids, a reduction in dosage may be advisable in hypothyroidism. Use with caution in opioid-dependent patients and in patients with hypotension, hypovolaemia, diseases of the biliary tract, pancreatitis, inflammatory bowel disorders, prostatic hypertrophy, adrenocortical insufficiency (Addison's disease), toxic psychosis, chronic pulmonary, renal or hepatic disease, myxoedema and debilitated elderly or infirm patients or patients taking benzodiazepines, other CNS depressants (including alcohol) or MAO inhibitors. As with all opioid preparations, patients who are to undergo cordotomy or other pain-relieving surgical procedures should not receive OxyNorm capsules or liquid for 6 hours before surgery. As with all opioid preparations, OxyNorm capsules or liquid should be used with caution following abdominal surgery as opioids are known to impair intestinal motility and should not be used until the physician is assured of normal bowel function. Should paralytic ileus be suspected or occur during use, OxyNorm capsules or liquid should be discontinued immediately.

Hyperalgesia that will not respond to a further dose increase of oxycodone may very rarely occur in particular at high doses. An oxycodone dose reduction or change in opioid may be required.

Opioids, such as oxycodone hydrochloride, may influence the hypothalamic-pituitary-adrenal or –gonadal axes. Some changes that can be seen include an increase in serum prolactin and decreases in plasma cortisol and testosterone. Clinical symptoms may manifest from these hormonal changes.

Drug dependence

As with other opioids, tolerance and physical dependence tend to develop upon repeated administration of oxycodone. There is potential for abuse of the drug and for development of strong psychological dependence. OxyNorm capsules or liquid should therefore be prescribed and handled with a high degree of caution appropriate to the use of a drug with strong abuse potential.

In the absence of a clear indication for a strong opioid analgesic, drug-seeking behaviour must be suspected and resisted, particularly in individuals with a history of, or propensity for, drug abuse. Withdrawal symptoms may occur following abrupt discontinuation of oxycodone therapy or upon administration of an opioid antagonist. Therefore, patients on prolonged therapy should be withdrawn gradually from the drug if it is no longer required for pain control.

Oxycodone should be used with caution and under close supervision in patients with pain not due to malignancy who have a prior history of substance abuse. In such cases, prior psychological assessment is essential and the prescribing doctor should consider that the benefit of treatment outweighs the risk of abuse. OxyNorm capsules and liquid are intended for oral use only. Parenteral injection can be expected to result in severe adverse reactions which may be fatal.

Effects on fertility

In reproductive toxicology studies, no evidence of impaired fertility was seen in male or female rats at oral oxycodone doses of 8 mg/kg/day, with estimated exposure (plasma AUC) equivalent to 8 mg/day in men and 17 mg/day in women.

Despite these fertility studies in animals, prolonged use of opioids may result in impairment of reproductive function, including fertility and sexual dysfunction in both sexes, and irregular menses in women.

Use in pregnancy

Australian Pregnancy Category C: Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible.

Oxycodone used during pregnancy or labour may cause withdrawal symptoms and/or respiratory depression in the newborn infant. Oral administration of oxycodone during the period of organogenesis did not elicit teratogenicity or embryofetal toxicity in rats or rabbits at doses up to 8 mg/kg/day in rats (equivalent to 17 mg/day in women, based on estimated plasma AUC values) or 125 mg/kg/day in rabbits.

Oral administration of oxycodone to rats from early gestation to weaning did not affect postnatal development parameters at doses up to 6 mg/kg/day (equivalent to 9 mg/day in women, based on estimated AUC values). In a study designed specifically to investigate the effect of pre-natal oxycodone on the hypothalamic-pituitary-adrenal axis in adolescent rats, intravenous administration of oxycodone 0.8 mg/kg/day (equivalent to 11 mg/day in pregnant women, based on estimated AUC values) had no effect on the corticosterone response, but delayed and enhanced the peak ACTH response to corticotrophin releasing hormone in males, but not females. The clinical significance of this observation is unknown.

There are no adequate and well-controlled studies with oxycodone in pregnant women. Because animal reproduction studies are not always predictive of human responses, oxycodone should not be used during pregnancy unless clearly needed. Prolonged use of oxycodone during pregnancy can result in neonatal opioid syndrome. Oxycodone is not recommended for use in women during or immediately prior to labour. Infants born to mothers who have received opioids during pregnancy should be monitored for respiratory depression.

Use in lactation

Oxycodone accumulates in human milk, with a median maternal milk:plasma ratio of 3:1 . Oxycodone (7.5 ng/mL) was detected in the plasma of one of forty-one infants 72 hours after Caesarean section. Opioids may cause respiratory depression in the newborn and withdrawal symptoms can occur in breastfeeding infants when maternal administration of an opioid analgesic is stopped. OxyNorm capsules or liquid should not be used in breastfeeding mothers unless the benefits outweigh the risks. Breastfed infants should be monitored for respiratory depression, sedation, poor attachment and gastrointestinal signs.

Special Risk Groups

Use in renal and hepatic impairment

In renal and hepatic impairment, the administration of OxyNorm capsules or liquid does not result in significant levels of active metabolites. However, the plasma concentration of oxycodone in this patient population may be increased compared with patients having normal renal or hepatic function. Therefore, initiation of dosing in patients with renal impairment (CLcr < 60 mL/min) or hepatic impairment should be reduced to $^1/_3$ to ½ of the usual dose with cautious titration.

Use in the elderly

The plasma concentrations of oxycodone are only nominally affected by age, being approximately 15% greater in elderly as compared with young subjects. There were no differences in adverse event reporting between young and elderly subjects.

Use in elderly, debilitated patients
As with other opioid initiation and titration, doses in elderly patients who are debilitated should be reduced to $^1/_3$ to ½ of the usual doses.

Gender
Female subjects have, on average, plasma oxycodone concentrations up to 25% higher than males on a body weight adjusted basis. The reason for this difference is unknown. There were no significant male/female differences detected for efficacy or adverse events in clinical trials.

Genotoxicity
Oxycodone was not genotoxic in bacterial gene mutation assays but was positive in the mouse lymphoma assay. In assays of chromosomal damage, genotoxic effects occurred in the human lymphocyte chromosomal aberration assay *in vitro,* but not in the *in vivo* bone marrow micronucleus assay in mice.

Carcinogenicity
Studies of oxycodone in animals to evaluate its carcinogenic potential have not been conducted.

Driving and operating dangerous machinery
Oxycodone may modify patients' reactions to a varying extent depending on the dosage and individual susceptibility. If affected, patients should not drive or operate machinery.

INTERACTIONS WITH OTHER MEDICINES

Anticholinergic agents
Concurrent use with oxycodone with anticholinergics or medications with anticholinergic activity (e.g. tricyclic antidepressants, antihistamines, antipsychotics, muscle relaxants and anti-Parkinson medications) may result in increased anticholinergic adverse effects, including an increased risk of severe constipation and/or urinary retention.

Antihypertensive agents
Hypotensive effects of these medications may be potentiated when used concurrently with oxycodone, leading to increased risk of orthostatic hypotension.

CNS depressants (including non-benzodiazepines sedatives or hypnotics, general anaesthetics, phenothiazines, other tranquillisers, alcohol, other opioids, benzodiazepines and neuroleptic drugs, etc.)
Concurrent use with oxycodone may result in increased respiratory depression, hypotension, profound sedation, death or coma. Caution is recommended and the dosage of one or both agents should be reduced. Intake of alcoholic beverages while being treated with OxyNorm capsules or liquid should be avoided because this may lead to more frequent undesirable effects such as somnolence and respiratory depression. Oxycodone hydrochloride containing products should be avoided in patients with a history of or present alcohol, drug or medicines abuse.

Coumarin derivatives
Although there is little substantiating evidence, opiate agonists have been reported to potentiate the anticoagulant activity of coumarin derivatives.

CYP2D6 and CYP3A4 inhibitors and inducers
Oxycodone is metabolised in part via the CYP2D6 and CYP3A4 pathways. The activities of these metabolic pathways may be inhibited or induced by various co-administered drugs or dietary elements, which may alter plasma oxycodone concentrations. Oxycodone doses may need to be adjusted accordingly. Drugs that inhibit CYP2D6 activity, such as paroxetine and quinidine, may cause decreased clearance of oxycodone which could lead to an increase in oxycodone plasma concentrations. Concurrent administration of quinidine does not alter the pharmacodynamic effects of oxycodone. CYP3A4 inhibitors such as macrolide antibiotics (e.g. clarithromycin), azole antifungal agents (e.g. ketoconazole), protease inhibitors (e.g. ritonavir) and grapefruit juice may cause decreased clearance of oxycodone which could lead to an increase in oxycodone plasma concentrations. Oxycodone metabolism may be blocked by a variety of drugs (e.g. cimetidine, certain cardiovascular drugs and antidepressants), although such blockade has not yet been shown to be of clinical significance with OxyNorm capsules or liquid.

CYP3A4 inducers, such as rifampin, carbamazepine, phenytoin and St. John's wort, may induce the metabolism of oxycodone and cause increased clearance of the drug, resulting in a decrease in oxycodone plasma concentrations.

Oxycodone did not inhibit the activity of P450 isozymes 2D6, 3A4, 1A2, 2A6, 2C19 or 2E1 in human liver microsomes *in vitro.* Non-clinical data *in vitro* and *in vivo* indicate that oxycodone can act as a P-glycoprotein substrate and can induce overexpression of P-glycoprotein in rats.

Metoclopramide
Concurrent use with oxycodone may antagonise the effects of metoclopramide on gastrointestinal motility.

Monoamine Oxidase Inhibitors (MAOIs)
Non-selective MAOIs intensify the effects of opioid drugs which can cause anxiety, confusion and significant respiratory depression. Severe and sometimes fatal reactions have occurred in patients concurrently administered MAOIs and pethidine. Oxycodone should not be given to patients taking non-selective MAOIs or within 14 days of stopping such treatment. As it is unknown whether there is an interaction between selective MAOIs (e.g. selegiline) and oxycodone, caution is advised with this drug combination.

Neuromuscular blocking agents
Oxycodone may enhance the effects of neuromuscular blocking agents resulting in increased respiratory depression.

Opioid agonist analgesics (including morphine, pethidine)
Additive CNS depressant, respiratory depressant and hypotensive effects may occur if two or more opioid agonist analgesics are used concurrently.

Opioid agonist-antagonist analgesics (including pentazocine, butorphanol, buprenorphine)
Mixed agonist/antagonist analgesics may reduce the analgesic effect of oxycodone and/or may precipitate withdrawal symptoms.

ADVERSE EFFECTS

Immediate release formulations such as OxyNorm capsules or liquid may have a higher incidence of some adverse reactions than controlled release formulations such as OxyContin

tablets. Adverse drug reactions are typical of full opioid agonists, and tend to reduce with time, with the exception of constipation. Anticipation of adverse drug reactions and appropriate patient management can improve acceptability.

Cardiac disorders
Uncommon bradycardia, chest pain, ST depression, palpitations (as part of withdrawal syndrome), supraventricular tachycardia

Ear and labyrinth disorders
Common vertigo
Uncommon tinnitus

Eye disorders
Common miosis, visual impairment

Gastrointestinal disorders
Very common nausea, vomiting, constipation
Common abdominal pain, diarrhoea, dry mouth, dyspepsia, gastritis, hiccup
Uncommon colic, dental caries, dysphagia, eructation, flatulence, gastrointestinal disorder, ileus, stomatitis

General disorders and administration site conditions
Common asthenia, fatigue, chills, fever
Uncommon accidental injury, drug tolerance, drug withdrawal syndrome (with or without seizures), oedema, peripheral oedema, malaise, facial flushing, lymphadenopathy, muscular rigidity, neck pain, pain, thirst
Not known drug withdrawal syndrome neonatal

Hepatobiliary disorders
Uncommon biliary spasm, cholestasis, hepatic enzyme increased

Immune system disorders
Uncommon allergic reaction, anaphylactic reaction, anaphylactoid reaction, hypersensitivity

Metabolism and nutrition disorders
Common decreased appetite
Uncommon increased appetite, dehydration, hyponatraemia

Nervous system disorders
Very common dizziness, headache, somnolence
Common faintness, sedation, twitching, tremor, lethargy
Uncommon abnormal gait, amnesia, drowsiness, hyperkinesia, hypertonia, hypoaesthesia, hypothermia, muscle contractions involuntary, paraesthesia, raised intracranial pressure, seizures, speech disorder, stupor, syncope, dysgeusia (taste perversion), convulsion
Not known hyperalgesia

Psychiatric disorders

Common	abnormal dreams, anxiety, confusional state, insomnia, nervousness, thinking abnormal, depression
Uncommon	affect lability, agitation, disorientation, drug dependence, dysphoria, euphoric mood, hallucination, libido decreased, mood altered, restlessness
Not known	aggression

Renal and urinary disorders

Uncommon	ureteric spasm, urinary abnormalities, urinary infection, urinary retention

Reproductive system and breast disorders

Uncommon	amenorrhea, erectile dysfunction, hypogonadism

Respiratory, thoracic and mediastinal disorders

Common	bronchospasm, dyspnoea, pharyngitis, voice alteration
Uncommon	respiratory depression

Skin and subcutaneous tissue disorders

Very common	pruritus
Common	hyperhidrosis, rash.
Uncommon	angioedema, dry skin, exfoliative dermatitis, urticaria and other skin rashes

Vascular disorders

Common	orthostatic hypotension.
Uncommon	hypotension, migraine, vasodilatation

Key: *Very common* (≥ 1/10)
Common (≥ 1/100 to <1/10)
Uncommon (≥ 1/1000 to <1/100)
Rare (≥ 1/10,000 to < 1/1,000)
Very rare (< 1/10,000)
Not known (cannot be estimated from the available data)

If nausea and vomiting are troublesome oxycodone may be combined with an antiemetic. Constipation must be treated with appropriate laxatives. Overdose may produce respiratory depression. Compared with other opioids oxycodone is associated with low histamine release although urticaria and pruritus may occur.

DOSAGE AND ADMINISTRATION

OxyNorm oral dose forms may not be interchangeable with Endone tablets.
OxyNorm capsules should be swallowed whole and not opened, chewed or crushed.

Limited data suggest that food may significantly increase the amount of oxycodone absorbed from an oral solution – see Pharmacokinetics, *Absorption.*

Alcoholic beverages should be avoided by patients while being treated with OxyNorm capsules or liquid.

Non-malignant pain: In common with other strong opioids, the need for continued treatment should be assessed at regular intervals.

Adults, elderly and children over 18 years: Prior to initiation and titration of doses, refer to the **PRECAUTIONS** section for information on special risk groups such as females and the elderly.

OxyNorm capsules or liquid should be taken at 4-6 hourly intervals. The dosage is dependent on the severity of the pain, and the patient's previous history of analgesic requirements.

Increasing severity of pain will require an increased dosage of OxyNorm capsules or liquid. The correct dosage for any individual patient is that which controls the pain and is well tolerated throughout the dosing period. Patients should be titrated to pain relief unless unmanageable adverse drug reactions prevent this.

OxyNorm capsules or liquid will generally be used in a short-term trial (4-6 weeks) to determine if the pain is opioid responsive, before transferring to a longer-acting oxycodone preparation such as OxyContin tablets, in accordance with the clinical guidelines on the use of opioid analgesics in such patients (e.g. those published by the Australian Pain Society in the Medical Journal of Australia 1997;167:30-4). However, OxyNorm liquid may be used longer term in patients unable to take solid oral dosage forms, or when more precise dose titration is necessary.

The usual starting dose for opioid-naive patients or patients presenting with severe pain uncontrolled by weaker opioids is 5 mg 4-6 hourly. The dose should then be carefully titrated, as frequently as once a day if necessary, to achieve pain relief. The majority of patients will not require a daily dose greater than 400 mg. However, a few patients may require higher doses.

Patients receiving oral morphine before oxycodone therapy should have their daily dose based on the following ratio: 10 mg of oral oxycodone is equivalent to 20 mg of oral morphine. It must be emphasised that this is only a guide to the dose of OxyNorm capsules or liquid required. Inter-patient variability requires that each patient be carefully titrated to the appropriate dose.

Controlled pharmacokinetic studies in elderly patients (aged over 65 years) have shown that compared with younger adults, the clearance of oxycodone is only slightly reduced. No untoward adverse drug reactions were seen based on age, therefore adult doses and dosage intervals are appropriate.

Adults with mild to moderate renal impairment and mild hepatic impairment: The plasma concentration in this patient population may be increased. Therefore, dose initiation should follow a conservative approach (refer to the PRECAUTIONS section).

Children under 18 years: OxyNorm capsules or liquid should not be used in patients under 18 years.

*Multiplication Factors for Converting the Daily Dose of Prior Opioids to the Daily Dose of Oral Oxycodone**
(mg/Day Prior Opioid x Factor = mg/Day Oral Oxycodone)

	Oral Prior Opioid	**Parenteral Opioid**
Oxycodone	1	--
Codeine	0.15	--
Hydromorphone	4	20
Pethidine (Meperidine)	0.1	0.4
Methadone	1.5	3
Morphine	0.5	3

* To be used for conversion to oral oxycodone. For patients receiving high-dose parenteral opioids, a more conservative conversion is warranted. For example, for high-dose parenteral morphine, use 1.5 instead of 3 as a multiplication factor.

OVERDOSAGE

Symptoms: Acute overdosage with oxycodone can be manifested by respiratory depression (reduced respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, hypotonia, cold and/or clammy skin, miosis (dilated if hypoxia is severe), and sometimes bradycardia, hypotension, pulmonary oedema, and death. Severe overdose may result in apnoea, pulmonary oedema, circulatory collapse and death.

Treatment of oxycodone overdosage: Primary attention should be given to immediate supportive therapy with the establishment of adequate respiratory exchange through the provision of a patent airway and institution of assisted or controlled ventilation. Adequate body temperature and fluid balance should be maintained. Oxygen, intravenous fluids, vasopressors and other supportive measures should be used as indicated, to manage the circulatory shock accompanying an overdose. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

Activated charcoal may reduce absorption of the drug if given within one or two hours after ingestion. Administration of activated charcoal should be restricted to patients who are fully conscious with an intact gag reflex or protected airway. A saline cathartic or sorbitol added to the first dose of activated charcoal may speed gastrointestinal passage of the product. In patients who are not fully conscious or have an impaired gag reflex, consideration should be given to administering activated charcoal via a nasogastric tube, once the airway is protected.

If there are signs of clinically significant respiratory or cardiovascular depression, the use of an opioid antagonist should be considered. The opioid antagonist naloxone hydrochloride is a specific antidote for respiratory depression due to overdosage or as a result of unusual sensitivity. The usual intravenous adult dose of naloxone is 0.4 mg or higher (please refer to naloxone product information for more information). The onset of naloxone effect may be delayed by 30 minutes or more. Concomitant efforts at respiratory resuscitation should be carried out. Since the duration of action of oxycodone may exceed that of the antagonist, the patient should be under continued surveillance and doses of the antagonist should be repeated as needed, or an antagonist infusion established, to maintain adequate respiration.

In an individual physically dependent on, or tolerant to, opioids, the administration of the usual dose of opioid antagonist will precipitate an acute withdrawal syndrome. The severity of this

syndrome will depend on the degree of physical dependence and the dose of antagonist administered. The use of opioid antagonists in such individuals should be avoided if possible. If an opioid antagonist must be used to treat serious respiratory depression in the physically dependent patient, the antagonist should be administered with extreme care by using dosage titration, commencing with 10 to 20% of the usual recommended initial dose.

Toxicity: Oxycodone toxicity may result from overdosage but because of the great interindividual variation in sensitivity to opioids it is difficult to determine an exact dose of any opioid that is toxic or lethal. The toxic effects and signs of overdosage may be less pronounced than expected, when pain and/or tolerance are manifest.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26.

PRESENTATION AND STORAGE CONDITIONS

Presentation

OxyNorm Capsules:
OxyNorm® capsules 5 mg (orange/beige), 10 mg (white/beige), 20 mg (pink/beige), in blister packs of 20 and 60 capsules.
OxyNorm® capsules 5 mg (orange/beige), in blister packs of 10 capsules.
OxyNorm® capsules 5 mg (orange/beige), 10 mg (white/beige), 20 mg (pink/beige), in bottle packs of 20 capsules and 60 capsules.

OxyNorm Oral liquid:
OxyNorm® liquid 1 mg/ mL is a clear, colourless to straw coloured solution in bottles of 250 mL.

Not all presentations may be marketed.

Storage conditions
Store below 30ºC.

NAME AND ADDRESS OF THE SPONSOR
Mundipharma Pty Limited
ABN 87 081 322 509
88 Phillip Street
SYDNEY, NSW 2000

Further information may be obtained from Mundipharma's Medical Information Department 1800 188 009.

POISON SCHEDULE OF THE MEDICINE: S8

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (the ARTG)

OxyNorm® capsules 5 mg, 10 mg, 20 mg: 08 November 2000
OxyNorm® liquid 1 mg/ mL: 12 December 2001

DATE OF MOST RECENT AMENDMENT

17 October 2018

Orbis AU-4728