

# OXYNORM<sup>®</sup> CAPSULES

Oxycodone hydrochloride (5mg, 10mg)

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## What OxyNorm<sup>®</sup> is used for

These capsules have been prescribed for you by your doctor to relieve moderate to severe pain..

## How OxyNorm<sup>®</sup> works

They contain the active ingredient oxycodone which belongs to a group of medicines called strong analgesics or 'painkillers'.

## Before you take OxyNorm<sup>®</sup>

### -When you must not use it

Do not take OxyNorm<sup>®</sup> capsules if you:

- are allergic (hypersensitive) to oxycodone or any of the ingredients of the capsules (see section 7 'Product description') or have previously had an allergic reaction when taking other strong analgesics or painkillers (such as morphine or other opioids);
- have breathing problems, such as obstructive airways disease, acute asthma or breathing more slowly or weakly than expected;
- have a heart problem after long-term lung disease (cor pulmonale), suffer from irregular or fast heartbeats or changes in the way the heart beats (cardiac arrhythmias), have decreased heart rate;
- have a condition where the small bowel does not work properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying) or you have sudden pain in your abdomen, persistent constipation;
- have severe kidney problems;
- have just drunk a large amount of alcohol, regularly drink large amounts of alcohol or have confusion and shaking due to stopping drinking alcohol;

- have a head injury, a brain tumour or have raised pressure within the head, brain or spinal cord;
- are severely drowsy or have a reduced level of consciousness;
- suffer from convulsion, fits or seizures, have too much carbon dioxide in the blood (hypercapnia);
- are taking a type of medicine known as a monoamine oxidase inhibitor, or you have taken this type of medicine in the last two weeks;
- are about to undergo a surgery.

### -Before you start take it

Before treatment with these capsules tell your doctor or pharmacist 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 increased;
- have low blood pressure (hypotension) including from having low blood volume;
- 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 bile duct;
- have inflammatory bowel disease;
- have increased prostate size or difficulty passing urine;
- 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;
- have kidney and liver disease;
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating when an individual stops alcohol or drug intake after prolonged period of excessive alcohol or drug intake;
- have abdominal problems or gall bladder or bile duct surgery, or have recently undergone an abdominal surgery
- are about to have an operation for pain relief in the next 6 hours;

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

you are taking these capsules.

These capsules should be avoided in patients with a history of, or present drug abuse.

### -Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you take these capsules with some other medicines, the effect of these capsules or the other medicine may be changed.

These capsules must not be used together with a monoamine oxidase inhibitor, or if you have taken this type of medicine in the last two weeks.

Tell your doctor or pharmacist if you are taking:

- medicines to relieve stomach cramps or spasms, to prevent travel sickness, to treat Parkinson's disease or to treat urinary incontinence;
- medicines to treat high blood pressure;
- medicines to help you sleep or stay calm (for example tranquillisers, hypnotics or sedatives);
- medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptic drugs);
- medicines to put you to sleep during an operation or procedure (general anaesthetics);
- medicines to thin the blood e.g. coumarin derivatives such as warfarin;
- medicines to stop nausea or vomiting e.g. metoclopramide
- medicines to treat depression, medicines to treat depression belonging to a group called monoamine oxidase inhibitors must be stopped 14 days before OxyNorm<sup>®</sup> capsules are taken;
- medicines to relax your muscles;
- other strong analgesics or painkillers, including other opioids (such as morphine, pethidine, butorphanol, pentazocine and buprenorphine);
- quinidine (a medicine to treat a fast heart beat);
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn);
- alcohol.

The 5 mg capsules contain sunset yellow (E110) which may cause allergic reactions.

Taking OxyNorm® with a benzodiazepine (medicine used as sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepines.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

#### *Pregnancy and breastfeeding*

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

#### *Pregnancy*

You should not use these capsules during pregnancy and labour unless you have been specifically told by your doctor. Depending on the dose and duration of therapy with oxycodone slow and shallow breathing (respiratory depression) may occur in the newborn infant.

#### *Breastfeeding*

These capsules should not be used while breastfeeding because the active ingredient can pass into breast milk.

#### *Driving and using machines*

These capsules may cause a number of side effects such as drowsiness which could affect your ability to drive or use machinery (see section 5 for a full list of side effects). These are usually most noticeable when you first start taking the capsules, or when changing to a higher dose. If you are affected you should not drive or use machinery.

#### **How to use OxyNorm®**

##### *-How much to use*

Always take these capsules exactly as your doctor has told you. The label on your medicine will tell you how many capsules to take and how often.

Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure. Swallow your capsules whole with a glass of water. Do not chew or crush them. You must only take the capsules by mouth.

##### *-When to use it*

*Elderly and adults over 18 years of age*

The usual starting dose is one 5 mg capsule every 4 to 6 hours. However, your doctor will prescribe the dose required to treat your pain. If you find that you are still in pain whilst taking these capsules discuss this with your doctor.

##### *Children under 18 years of age*

Children under 18 years of age should not take the capsules.

##### *Patients with kidney or liver problems*

Please tell your doctor if you suffer from kidney or liver problems as they may prescribe you an alternative medicine or a lower dose depending upon your condition.

##### *-How long to use it*

Continue taking your medicine for as long as your doctor tells you. You should not suddenly stop taking these capsules unless your doctor tells you to. If you want to stop taking your capsules, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects.

##### *-If you forget to use it*

If you miss a dose you should take the next dose as soon as you remember then carry on as before. Do not take two doses within 4 hours. Do not take a double dose to make up for forgotten capsules.

##### *-If you use too much (overdose)*

Call your doctor or hospital straight away. People who have taken an overdose may feel very sleepy, sick or dizzy and may also develop pinpoint pupils, breathing problems, low blood pressure or slow heart rate and lack muscle tone. In severe cases an overdose may lead to unconsciousness or even death. An overdose may result in a brain disorder (known as toxic leukoencephalopathy). When seeking medical attention make sure that you take this leaflet and any remaining capsules with you to show to the doctor.

If you have taken too many capsules under no circumstances should you put yourself in a situation that requires you to be alert e.g. driving a car.

#### **While you are taking it**

##### *-Things you must do*

Take OxyNorm® capsules exactly as your doctor has prescribed.

Before you start on a new medicine, remind your doctor and pharmacist that you are taking OxyNorm® capsules. Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Tell your doctor if your pain is getting worse. Always discuss any problems or difficulties you have while you are taking OxyNorm® capsules.

Tolerance to oxycodone may develop which means that the effect of the medicine may decrease. If this happens, your doctor may increase the dose so that you get adequate pain relief.

Keep enough OxyNorm® capsules with you to last over weekends and holidays..

##### *-Things you must not do*

Do not drink alcohol while you are taking OxyNorm® capsules.

Alcohol use could increase serious side effects of oxycodone, such as sleepiness, drowsiness, and slow or shallow breathing.

Do not take OxyNorm® capsules to treat any other complaint unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine, exceed the dose recommended or change the dosage without checking with your doctor.

Over time your body may become used to you taking oxycodone so if you stop taking it suddenly, your pain may worsen and you may have unwanted side effects such as withdrawal symptoms such as agitation, anxiety, shaking or sweating. This is called physical dependence.

If you need to stop taking this medicine, your doctor will gradually reduce the amount you take each day, if possible, before stopping the medicine completely.

***- Things to be careful of***

Do not drive or operate machinery until you know how OxyNorm® capsules affect you.

OxyNorm® capsules may cause drowsiness, dizziness, hallucinations, disorientation, blurred vision or other vision problems or may affect alertness. Discuss these aspects and any impact on your driving or operating machinery with your doctor.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Tell your doctor if you suffer from nausea or vomiting when taking OxyNorm® capsules.

If you vomit after your dose, your pain may come back, as you may not have absorbed your medicine. If this happens, speak to your doctor. Your doctor may prescribe some medicine to help you stop vomiting.

Tell your doctor if taking OxyNorm® capsules causes constipation.

Your doctor can advise you about your diet, the proper use of laxatives and suitable exercise you can do to help you manage this.

There is potential for abuse of oxycodone and the development of addiction to oxycodone. It is important that you discuss this issue with your doctor.

**Serotonin syndrome:** OxyNorm® may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

**Adrenal insufficiency:** Long-term use of OxyNorm® may cause adrenal insufficiency, a potential life-threatening condition that may be present with a non-specific symptoms

and signs such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.

**Infertility:** Long-term use of OxyNorm® may cause reduced fertility. It is not known whether these effects on fertility are reversible

**Side effects**

Like all medicines, these capsules can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are rare. 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).

As with all strong painkillers, there is a risk that you may become addicted or reliant on these capsules.

**Very common side effects** (probably affecting more than 1 in 10 people) are listed below:

- Constipation (your doctor can prescribe a laxative to overcome this problem).
- Feeling or being sick (this should normally wear off after a few days; however your doctor can prescribe an anti-sickness medicine if it continues to be a problem), vomiting.
- Headache, confusion, a feeling of unusual weakness, dizziness when you stand or stretch suddenly,

**Common side effects** (probably affecting more than 1 in 100 people) are listed below.

- Drowsiness (this is most likely when you start taking your capsules or when your dose is increased, but it should wear off after a few days).
- Dry mouth, loss of appetite, gastritis, hiccups, indigestion, abdominal pain or discomfort, diarrhea.
- sedation, anxiety, nervousness, twitching, difficulty in sleeping, abnormal thoughts or dreams.

- Difficulty in breathing or wheezing, shortness of breath, decreased cough reflex, sore throat, trouble swallowing or changes in voice.
- Rash, itchy skin.
- Sweating, fever, chills.

**Uncommon side effects** (probably affecting fewer than 1 in 100 people) are listed below.

- Difficulty in swallowing, inflammation of the mouth, belching, wind, gastrointestinal disorders (e.g. upset stomach), a condition where the bowel does not work properly (ileus), increase in appetite, change in taste,
- Severe headache or feel sick due to raise in pressure inside the skull, loss of consciousness.
- A blockage in the flow of bile from the liver. This can cause itchy skin, yellow skin, very dark urine and very pale stools.
- A feeling of dizziness or 'spinning', hallucinations, drowsiness, disorientation, mood changes, restlessness, fits or convulsions, increase pressure in the head skull, reduce body temperature, shivering, walk abnormally, agitation, depression, tingling or numbness, loss of memory, involuntary muscle contractions, unusual muscle stiffness or slackness reduced sensitivity to pain or touch, generally feeling unwell, a feeling of extreme happiness, reduced consciousness, difficulties with speech, seizures blurred vision.
- Withdrawal symptoms such as agitation, anxiety, shaking or sweating.
- Difficulty in passing urine, infection in the urinary tract, urinary infection, biliary or ureteric spasm, impotence, decreased sexual drive, absence of menstrual periods.
- Fast, irregular heartbeat, low blood pressure, flushing of the skin, chest pain.
- Dehydration, thirst, swelling of the hands, ankles or feet.
- Shallow or difficult breathing.
- Dry skin, severe flaking or peeling of the skin.
- Prone to accidental injuries, may experience pain including neck pains
- Redness of the face, reduction in size of the pupils in the eye, muscle

stiffness, swollen lymph nodes, allergic reaction

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### Storage and Disposal of OxyNorm®

#### -Storage

Keep out of the reach and sight of children. Accidental overdose by a child is dangerous and may be fatal. Do not use any capsules after the expiry date which is stated on the blister and carton. Do not store your capsules above 30°C.

#### -Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### Product Description

#### -What it looks like

The capsules have a hard gelatin shell. OxyNorm® capsules 5 mg are orange/beige, printed ONR 5. OxyNorm® capsules 10 mg are white/beige, printed ONR 10. These are available in cartons containing 28 capsules (two blister stripes of 14 capsules).

#### -Ingredients

##### Active ingredient

The active ingredient is oxycodone hydrochloride.

OxyNorm® capsules 5 mg contains 5mg of oxycodone hydrochloride.

OxyNorm® capsules 10 mg contains 10mg of oxycodone hydrochloride.

##### Inactive ingredients

The inactive ingredients are:

- Microcrystalline cellulose
- Magnesium stearate

The ingredients used for the capsules are:

- Sodium lauryl sulfate

- Gelatin

The colouring agents used for the capsules are:

- Indigo carmine (E132)
- Iron oxide red (E172)
- Iron oxide yellow (E172)
- Titanium dioxide (E171)
- Sunset Yellow (E110) which is only present in the OxyNorm® capsules 5 mg

#### -MAL number

OxyNorm® capsules 5mg –

MAL10070560ACZ

OxyNorm® capsules 10mg –

MAL10070561ACZ

### Manufacturer

Bard Pharmaceuticals Limited,  
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### Product Registration Holder

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