PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

OxyNorm® 5 mg Capsules

OxyNorm® 10 mg Capsules

OxyNorm® 20 mg Capsules

Active substance

Oxycodone hydrochloride

Sugar / sweetener status

The capsules are sugar free.

This medicine contains oxycodone which is an opioid, which can cause addiction.

You can get withdrawal symptoms if you stop taking it suddenly.

Read all of this leaflet carefully before you start taking OxyNorm® Capsules

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- OxyNorm® Capsules 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 OxyNorm® Capsules are and what it is used for
2. What you need to know before you take OxyNorm® Capsules
3. How to take OxyNorm® Capsules
4. Possible side effects
5. How to store OxyNorm® Capsules
6. Contents of the pack and other information

1. What OxyNorm® Capsules are and what it is used for

OxyNorm® Capsules are a strong analgesic or “painkiller” and belongs to the opioid group.

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

OxyNorm® Capsules are used for the relief of severe pain requiring the use of a strong opioid analgesic.

2. What you need to know before you take OxyNorm® Capsules

Do not take OxyNorm® Capsules:

- if you are allergic (hypersensitive) to the active ingredient oxycodone hydrochloride, or any of the other ingredients (see “What OxyNorm® Capsules contain”);
- if you suffer from severe breathing problems with a lowered supply of oxygen to the blood (hypoxia) and/or increased carbon dioxide saturation of the blood (hypercapnia);
- if you suffer from a long-term (chronic) obstructive lung disease;
- if you have a heart problem after long-term lung disease (cor pulmonale);
- if you suffer from long-term (chronic) bronchial asthma;
- where the small bowel does not work properly (paralytic ileus);
- during pregnancy and breastfeeding;

- in the presence of moderate to 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 (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid) (see “Other medicines and OxyNorm® Capsules”);
- 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).

Warnings and precautions

Take special care with OxyNorm® Capsules:

- if you have breathing problems;
- if you are elderly or debilitated (weak);
- if you have an under-active thyroid (hypothyroidism), as you may need a lower dose of OxyNorm® Capsules;
- if you have sleep apnoea (a sleep disorder in which breathing repeatedly stops and starts);
- 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 difficulty breathing;
- if you have had abdominal (stomach) surgery;
- if you have low blood pressure (hypotension) or low blood volume (hypovolemia);
- if you have inflammatory bowel disease;
- for 6 hours before an operation and within the first 12-24 hours post-operatively.

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 OxyNorm® 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 OxyNorm® 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 OxyNorm® , 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 OxyNorm® Capsules).

Increased sensitivity to pain that does not respond to dose increases can rarely develop. If this happens, your doctor will reduce your dose or switch you to an alternative opioid painkiller.

Long-term use of OxyNorm® Capsules may require continual dose increases to achieve the desired pain relief. Long-term use of OxyNorm® Capsules may lead to physical and psychological dependence (addiction) and a withdrawal syndrome may occur when treatment is stopped suddenly. When you no longer require treatment with OxyNorm® Capsules, you may require gradual decrease of the dose to prevent symptoms of withdrawal.

Children and Adolescents under 18 years of age:

OxyNorm® Capsules have not been tested in children and adolescents under 18 years of age. Therefore safety and efficacy are not established and OxyNorm® Capsules are not

recommended in children and adolescents under 18 years of age.

Other medicines and OxyNorm® Capsules

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

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

OxyNorm® Capsules 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 “Do not take OxyNorm® Capsules”), 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 treat anxiety or to help you sleep (for example tranquillisers, hypnotics or sedatives);
- have recently been given an anaesthetic;
- are taking medicines to treat depression;
- are taking medicines to treat psychiatric or mental disorders;
- are taking other strong analgesics or ‘painkillers’;
- are taking muscle relaxants;
- are taking medicines to treat high blood pressure;
- are taking quinidine (a medicine to treat a fast heart beat);
- are taking cimetidine (a medicine for stomach ulcers, indigestion or heartburn);
- are taking antifungal medicines (such as ketoconazole);
- are taking antibiotics (such as erythromycin);
- are taking medicine to treat HIV (such as ritonavir);

- are taking medicine to treat tuberculosis (such as rifampicin);
- are taking medicine to treat epilepsy (such as carbamazepine or phenytoin);
- medicines with anticholinergic actions (such as antihistamines, antipsychotics and anti-Parkinson medicines);
- St. John's Wort.

Using OxyNorm® Capsules 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.

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

OxyNorm® Capsules with food and drink

You can take OxyNorm® Capsules with or without food.

Drinking alcohol during your treatment with OxyNorm® Capsules 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.

Do not take OxyNorm® Capsules during pregnancy. The active ingredient oxycodone is transported through the placenta. The long-term use of OxyNorm® Capsules during pregnancy may lead to withdrawal symptoms in newborn infants and may result in breathing problems.

Do not take OxyNorm® Capsules while breastfeeding, since the active ingredient oxycodone may pass into the breastmilk.

Driving and using machines

You may feel sleepy when you first start taking OxyNorm® Capsules, 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 OxyNorm® Capsules 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 OxyNorm® Capsules affects them.

OxyNorm® Capsules contains:

Magnesium stearate and microcrystalline cellulose.

The capsule shells contain: gelatine, indigo carmine (E132), iron oxide (E172), sodium laurylsulphate and titanium dioxide (E171).

In addition, the 5 mg capsules contains Sunset Yellow (E110).

The 5 mg capsules contains Sunset Yellow (E110) which may cause allergic reactions.

The capsules are sugar free.

3. How to take OxyNorm® Capsules

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 OxyNorm®.

Always take OxyNorm® Capsules exactly as your doctor has told you. Check with your doctor

or pharmacist if you are not sure. Your doctor will tell you how long your treatment with OxyNorm® Capsules will last. Do not stop treatment early because it may lead to withdrawal symptoms. If you feel that the effect of OxyNorm® Capsules is too weak or too strong, tell your doctor or pharmacist.

Unless otherwise prescribed by your doctor, the usual starting dose for adults older than 18 years, is one capsule of OxyNorm® 5 mg Capsules (5 mg oxycodone hydrochloride) every 4 – 6 hours. However, your doctor will prescribe the dose required to treat your pain based on your situation.

Swallow the capsules whole with water. Do not chew or crush them.

You must only take OxyNorm® Capsules by mouth. The capsule contents should never be injected as this may lead to serious side effects, which may be fatal.

If you take more OxyNorm® Capsules than you should

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

People who have taken an overdose may feel very sleepy and sick. 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 capsules with you to show to the doctor.

If you forget to take OxyNorm® Capsules

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 a forgotten dose.

If you stop taking OxyNorm® Capsules

Do not stop taking OxyNorm® Capsules without telling your doctor.

If you want to stop taking your capsules, discuss this with your doctor first. Your doctor will tell you how to reduce the dose gradually, so you do not experience unpleasant effects.

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

4. Possible side effects

OxyNorm® Capsules can have side effects.

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

As with all strong painkillers, there is a risk that you may become addicted or reliant on OxyNorm® Capsules.

If any of the following happens, stop taking OxyNorm® Capsules, tell your doctor immediately or go to the closest casualty department or nearest hospital:

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).

Frequent side effects

(Probably affecting more than 1 in 100 people taking OxyNorm® Capsules).

Most people will have constipation when they take OxyNorm® Capsules. Your doctor can prescribe a laxative to overcome this problem.

You may feel sick or vomit (be sick) when you take these capsules, this should normally wear off after a few days however your doctor can prescribe an anti-vomiting medicine if it continues to be a problem.

You may find that you feel sleepier than normal when you start taking your capsules or when your dose is increased. This should wear off after a few days.

The following side effects have also been commonly reported in patients treated with OxyNorm® Capsules:

- 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

(Probably affecting fewer than 1 in 100 people taking OxyNorm® Capsules)

- Hypersensitivity reactions;
- Inflamed mouth, oral ulcers, gum bleeding;
- Belching, wind, 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, restlessness, 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;
- Pain (e.g. chest pain);
- Dehydration, thirst, swelling of the hands, ankles or feet;
- Changes in body weight (loss or rise);
- 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 OxyNorm® Capsules to gain the same level of pain relief (tolerance);
- Sleep apnoea syndrome (a condition where breathing repeatedly stops and starts while sleeping);
- 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 OxyNorm® Capsules.

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 generalised allergic reactions (anaphylactic and anaphylactoid reactions);
- Absence of menstrual periods;
- Withdrawal symptoms in newborn infants.

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 OxyNorm® Capsules.

Alternatively report to: ZADrugSafety@mundipharma.co.za

5. How to store OxyNorm® Capsules

Store all medicines out of reach of children.

Store at or below 30 °C. Store in original package in the outer carton in order to protect from light.

Do not use OxyNorm® Capsules after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (i.e. toilets).

6. Contents of the pack and other information

What OxyNorm® Capsules contain

The active ingredient is oxycodone (as oxycodone hydrochloride).

Each OxyNorm® 5 mg Capsules contains 5 mg of oxycodone hydrochloride.

Each OxyNorm® 10 mg Capsules contains 10 mg of oxycodone hydrochloride.

Each OxyNorm® 20 mg Capsules contains 20 mg of oxycodone hydrochloride.

The other ingredients are magnesium stearate and microcrystalline cellulose.

The capsule shells contain: gelatine, indigo carmine (E132), iron oxide (E172), sodium laurylsulphate and titanium dioxide (E171).

In addition, the 5 mg capsules contains Sunset Yellow (E110).

The capsules are sugar free.

What OxyNorm® Capsules looks like and contents of the pack

OxyNorm® 5 mg Capsules (capsule size 4) has an orange body and beige cap imprinted with ONR 5 in black ink, and filled with white to off-white powder.

OxyNorm® 10 mg Capsules (capsule size 4) has a white body and beige cap imprinted with ONR 10 in black ink, and filled with white to off-white powder.

OxyNorm® 20 mg Capsules (capsule size 4) has a pink body and beige cap imprinted with ONR 20 in black ink, and filled with white to off-white powder.

OxyNorm® Capsules are supplied in clear PVdC coated PVC and aluminium foil blister packs of 28.

Holder of Certificate of Registration

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OxyNorm® 20 mg Capsules: 12/2.9/0258

Botswana: S1A

OxyNorm® 5 mg Capsules: BOT1402578

OxyNorm® 10 mg Capsules: BOT1402579

OxyNorm® 20 mg Capsules: BOT1402580

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.

® = OxyNorm® is a registered trademark