

Package leaflet: Information for the user

OxyNorm® concentrate 10 mg/ml oral solution

Oxycodone hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What *OxyNorm* concentrate is and what it is used for

OxyNorm concentrate is a strong analgesic or “painkiller” and belongs to the group of opioids.

OxyNorm concentrate is used in adults and adolescents from 12 years and older for the relief of severe pain, which can be adequately managed only with opioid analgesics.

2. What you need to know before you take *OxyNorm* concentrate

Do not take *OxyNorm* concentrate if you:

- are allergic (hypersensitive) to oxycodone or any of the other ingredients of the medicine (listed in section 6 ‘Further information’) 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 chronic severe obstructive lung disease, severe bronchial asthma or severe respiratory depression. Symptoms may include breathlessness, coughing or breathing more slowly and weakly than expected;
- have a head injury that causes a severe headache or makes you feel sick. This is because this medicine may make these symptoms worse or hide the extent of the head injury;
- have a condition where the bowel does not work properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying) or you have severe sudden pain in your abdomen (acute abdomen);
- have a heart problem after long-term lung disease (cor pulmonale).

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- are elderly or weakened;
- have an under-active thyroid gland (hypothyroidism);
- have myxoedema (a thyroid disorder, with dryness, coldness, and swelling [‘puffiness’] of the skin, affecting the face and limbs);
- have a severe headache or feel sick as this may indicate that the pressure in your skull is increased;
- have low blood pressure (hypotension);
- have inflammation of the pancreas (which may cause severe pain in the abdomen and back), problems with your gall bladder or bile duct;
- have a blockage of the gut or an inflammatory bowel disorder;
- have colicky abdominal pain or discomfort;

- 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) for example Addison's disease;
- have breathing problems such as severely impaired respiratory function, chronic obstructive airways disease, severe lung disease or reduced respiratory reserve. Symptoms may include breathlessness and coughing;
- have kidney or liver problems;
- or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction");
- are a smoker;
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses;
- have withdrawal symptoms such as agitation, anxiety, palpitations, shaking or sweating upon stopping taking alcohol or drugs;
- suffer from seizures, fits or convulsions;
- are feeling light-headed or faint;
- need to take increasingly higher doses of *OxyNorm* concentrate to gain the same level of pain relief (tolerance);
- have an increase in sensitivity to pain;
- are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks;
- suffer from constipation.

Sleep-related breathing disorders

OxyNorm concentrate can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Opioids are not the first choice of treatment for pain not related to cancer and are not recommended as the only treatment. Other medicines should be used in the treatment of chronic pain along with opioids. Your doctor should monitor you closely and make necessary adjustments to your dose while you are taking *OxyNorm* concentrate to prevent addiction and abuse.

Tolerance, dependence and addiction

This medicine contains oxycodone, which is an opioid. It can cause dependence and/or addiction.

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

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

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

This medicine should never be injected as this may lead to serious side effects, which may be fatal.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Other medicines and *OxyNorm* concentrate

Concomitant use of opioids, including oxycodone and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe *OxyNorm* concentrate together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you take this medicine with some other medicines, the effect of this medicine or the other medicine may be changed.

The risk of side effects increases, if you use antidepressants (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 doctor or pharmacist if you 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 (see 'Warnings and precautions');
- medicines to help you sleep or stay calm (for example tranquilisers, hypnotics or sedatives, including benzodiazepines);

- medicines to treat depression (for example paroxetine or fluoxetine);
- medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptic drugs);
- medicines to treat epilepsy, pain, and anxiety such as gabapentin and pregabalin;
- other strong analgesics ('painkillers');
- muscle relaxants;
- medicines to treat high blood pressure;
- quinidine (a medicine to treat a fast heart beat);
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn);
- medicines to treat fungal infections (such as ketoconazole, voriconazole, itraconazole, or posaconazole);
- medicines used to treat bacterial infections (such as clarithromycin, erythromycin or telithromycin);
- a specific type of medicine known as a protease inhibitor to treat HIV (examples include boceprevir, ritonavir, indinavir, nelfinavir or saquinavir);
- 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);
- antihistamines;
- medicines to treat Parkinson's disease.

Also, tell your doctor if you have recently been given an anaesthetic.

Taking *OxyNorm* concentrate with food, drink and alcohol

This medicine may be taken with or without food. It may be mixed with a soft drink to make it easier to take.

Drinking alcohol during your treatment with this medicine 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 consciousness. It is recommended not to drink alcohol while you are taking *OxyNorm* concentrate. You should avoid drinking grapefruit juice during your treatment with *OxyNorm* concentrate.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You should not use this medicine 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) or withdrawal symptoms may occur in the newborn infant.

Breastfeeding

This medicine should not be used while breastfeeding because the active ingredient may pass into breast milk.

Driving and using machines

This medicine may cause a number of side effects such as drowsiness which could affect your ability to drive or use machinery (see section 4 for a full list of side effects). These are usually most noticeable when you first start taking the medicine, or when changing to a higher dose. If you are affected you should not drive or use machinery.

***OxyNorm* concentrate contains sodium saccharine, sodium citrate, sodium benzoate, sodium hydroxide and sunset yellow FCF (E110)**

This medicine contains 1.02 mg sodium (main component of cooking/table salt) in each milliliter. This is equivalent to 0.051% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 1 mg sodium benzoate in each ml. Benzoate salt may increase jaundice (yellowing of the skin and eyes) in new-born babies (up to 4 weeks old).

This medicine contains sunset yellow FCF (E110) which may cause allergic reactions.

3. How to take OxyNorm concentrate

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The label on your medicine will tell you how much to take and how often.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using *OxyNorm* concentrate, when and how long you need to take it, when to contact your doctor, and when you need to stop taking *OxyNorm* concentrate

Do not exceed the dose recommended by your doctor.

You must only take this medicine by mouth.

Adults and adolescents (from 12 years and older)

The usual starting dose is 5 mg every 6 hours. The dosing interval of *OxyNorm* concentrate may be reduced to 4 hours if required. *OxyNorm* concentrate should not be taken more than 6 times a day.

However, your doctor will prescribe the dose required to treat your pain. An oral syringe is supplied to help you measure your dose. Your medicine can be mixed with a soft drink to make it easier to take. If you find that you are still in pain whilst taking this medicine discuss this with your doctor.

Children below 12 years of age

Safety and efficacy of *OxyNorm* concentrate has not been tested sufficiently in children under 12 years of age. Therefore, treatment with *OxyNorm* concentrate is not recommended in children under 12 years of age.

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 lower dose depending upon your condition.

If you take more OxyNorm concentrate than you should or if someone accidentally swallows your medicine

Call your doctor or hospital straight away.

An overdose may result in:

- a reduction in size of pupils in the eye
- breathing more slowly or weakly than expected (respiratory depression)
- drowsiness or loss of consciousness
- low muscle tone (hypotonia)
- reduced pulse rate
- a fall in blood pressure
- difficulty in breathing due to fluid on the lungs (pulmonary oedema).
- a brain disorder (known as toxic leukoencephalopathy)

In severe cases an overdose may lead to unconsciousness or even death. When seeking medical attention make sure that you take this leaflet and any remaining medicine with you to show to the doctor.

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

If you forget to take OxyNorm concentrate

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* concentrate

You should not suddenly stop taking this medicine unless your doctor tells you to. If you want to stop taking your medicine, 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. Withdrawal symptoms such as yawning, abnormal dilation of the pupil of the eye, tear disorder, runny nose, agitation, anxiety, convulsions, difficulty in sleeping, palpitations, shaking or sweating may occur if you suddenly stop taking this medicine.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

This medicine can cause allergic reactions, although serious allergic reactions are reported in rare cases. 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 - a typical hazard of an opioid overdose).

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

Very common side effects: may affect more than 1 in 10 people

- 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).
- Drowsiness (this is most likely when you start taking your medicine or when your dose is increased, but it should wear off after a few days);
- Dizziness.
- Headache
- Itchy skin.

Common side effects: may affect up to 1 in 10 people

- Dry mouth, loss of appetite, indigestion, abdominal pain or discomfort, diarrhoea.
- Confusion, depression, a feeling of unusual weakness, shaking, lack of energy, tiredness, anxiety, nervousness, difficulty in sleeping, abnormal dreams, abnormal thoughts.
- Wheezing or difficulty in breathing, shortness of breath.
- Difficulty in passing urine.
- Rash.
- Sweating, high temperature.

Uncommon side effects: may affect up to 1 in 100 people

- A condition where you breathe more slowly or weakly than expected (respiratory depression).
- Difficulty in swallowing, belching, hiccups, wind, a condition where the bowel does not work properly (ileus), inflammation of the stomach, changes in taste, mouth ulcers, sore mouth.
- A condition which causes abnormal production of antidiuretic hormone (syndrome of inappropriate antidiuretic hormone secretion).
- A feeling of dizziness or 'spinning' (vertigo), hallucinations, mood swings, a feeling of extreme happiness, agitation, generally feeling unwell, loss of memory, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness, seizures, fits or convulsions, abnormal manner or style of walking, feeling detached from oneself, being unusually overactive, fainting, reduced consciousness, unusual muscle stiffness or slackness, involuntary muscle contractions.

- Impotence, decreased sexual drive, low levels of sex hormones in the blood (hypogonadism, seen in a blood test).
- Flushing of the skin.
- Dehydration, weight change, thirst, swelling of the hands, ankles or feet.
- Dry skin.
- Tear disorder, blurred vision, reduction in size of the pupils in the eye.
- A need to take increasingly higher doses to gain the same level of pain relief (tolerance).
- A ringing or buzzing sound in the ears.
- Swelling and irritation inside the nose, nose bleeds, voice alteration.
- Chills.
- Chest pain.
- Inability to fully empty the bladder.
- A worsening in liver function tests (seen in a blood test).
- Withdrawal symptoms (see section 3 'If you stop taking *OxyNorm* concentrate')

Rare side effects: may affect up to 1 in 1,000 people

- A feeling of 'faintness' especially on standing up.
- Low blood pressure.
- Hives.

Not known: frequency cannot be estimated from the available data

- Sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.
- Tooth decay.
- Colicky abdominal pain or discomfort.
- A problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction).
- A blockage in the flow of bile from the liver. This can cause itchy skin, yellow skin, very dark urine and very pale stools.
- Absence of menstrual periods.
- An increase in sensitivity to pain.
- Sleep apnoea (breathing pauses during sleep).
- Aggression.
- Long term use of *OxyNorm* concentrate 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance at www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store *OxyNorm* concentrate

Keep this medicine out of the sight and reach of children. Accidental overdose by a child is dangerous and may be fatal. Store this medicine in a locked safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month. EXP 08 2020 means that you should not take any of this medicine after the last day of August 2020.

Do not store your medicine above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What *OxyNorm* concentrate contains

The active ingredient is oxycodone hydrochloride. Each ml contains 10 mg of oxycodone hydrochloride.

The other ingredients are:

- Saccharin sodium
- Sodium benzoate (E211)
- Citric acid monohydrate
- Sodium citrate
- Hydrochloric acid
- Sodium hydroxide
- Purified water
- Sunset yellow FCF (E110)

What *OxyNorm* concentrate looks like and contents of the pack

This medicine is a clear orange solution.

Each bottle contains 30 or 120 ml of solution. Not all pack sizes may be marketed.
An oral syringe is also supplied with the bottle in a box.

Marketing Authorisation Holder

Mundipharma Pharmaceuticals Limited, United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland

Manufacturer

Mundipharma Pharmaceuticals Limited, 13 Othellos Street, Dhali Industrial Area, Nicosia, Cyprus, 2540 Cyprus

This leaflet is also available in large print, Braille or as an audio CD. To request a copy, please call the RNIB Medicine Information Line on:

0044 1733 37 53 70

You will need to give details of the product name and reference number.
These are as follows:

Product name: *OxyNorm* concentrate 10 mg/ml oral solution
Reference number: 1688/6/3

This medicinal product is authorised in the Member States of the EEA under the name:

Republic of Ireland *OxyNorm* Concentrate
Spain *OxyNorm* Concentrado

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