Package leaflet: Information for the patient

OxyNorm Dispersa® 5 mg, 10 mg and 20 mg orodispersible tablets
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 this leaflet:
1. What OxyNorm Dispersa tablets are and what they are used for
2. What you need to know before you take OxyNorm Dispersa tablets
3. How to take OxyNorm Dispersa tablets
4. Possible side effects
5. How to store OxyNorm Dispersa tablets
6. Contents of the pack and other information

1. What OxyNorm Dispersa tablets are and what they are used for

These tablets have been prescribed for you by your doctor to relieve severe pain over a period of 4 to 6 hours. They contain the active ingredient oxycodone which is a strong analgesic (‘painkiller’), which belongs to a group of medicines called opioids. These tablets are only for use in adults over 20 years of age.

You must talk to a doctor if you do not feel better or if you feel worse after a day.

2. What you need to know before you take OxyNorm Dispersa tablets

Do not take OxyNorm Dispersa tablets if you:

- are allergic (hypersensitive) to oxycodone or any of the other ingredients of the tablets (listed in section 6) or have previously had an allergic reaction when taking other strong painkillers (such as morphine or other opioids);
- have breathing problems, such as severe chronic obstructive lung disease, severe bronchial asthma or severe respiratory depression. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- have a head injury that causes a severe headache or makes you feel sick. This is because the tablets may make these symptoms worse or hide the extent of the head injury;
- have a condition where the bowel (part of your gut) does not work properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying) or you have sudden severe pain in your abdomen (acute abdomen);
- have a heart problem after long-term lung disease (cor pulmonale);

Children and adults under 20 years old should not take the tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking these tablets if you:

- 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);

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• 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 a mental disorder as a result of an intoxication (toxic psychosis);
• have inflammation of the pancreas (which may cause severe pain in the abdomen and back) or 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 pulmonary function, chronic obstructive airways disease, severe lung disease or reduced respiratory reserve. Symptoms may include breathlessness and coughing;
• have kidney or liver problems;
• are or have ever been addicted to alcohol or drugs, or have a known opioid dependence;
• have previously suffered from 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 Dispersa 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.

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

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

**Other medicines and OxyNorm Dispersa**

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 Dispersa together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

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.

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 these tablets with some other medicines, the effect of these tablets or the other medicine may be changed.

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 hypnotics or sedatives, including benzodiazepines);
• medicines to treat depression (for example paroxetine and fluoxetine);
• medicines to treat psychiatric or mental disorders (such as phenothiazines, antipsychotics or neuroleptic drugs);
• medicines to treat Parkinsons disease
• medicines to treat allergic reactions (antihistamines)
• medicines to stop or prevent vomiting (antiemetics)
• 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);
• antifungal medicines to treat fungal infections (such as ketoconazole, or voriconazole,itraconazole, or posaconazole);
• antibiotics used to treat 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)
• medicines to prevent your blood clotting or becoming too thick (coumarin anticoagulants).

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

**Taking OxyNorm Dispersa tablets with food, drink and alcohol**
Drinking alcohol during your treatment with these 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 consciousness. It is recommended not to drink alcohol while you’re taking OxyNorm Dispersa. You should avoid drinking grapefruit juice during your treatment with OxyNorm Dispersa.

**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 these tablets.

**Pregnancy**
You should not use these tablets 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**
These tablets should not be used while breastfeeding because the active ingredient may pass into breast milk.

**Driving and using machines**
These tablets 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 tablets, or when changing to a higher dose. If you are affected you should not drive or use machinery.

**OxyNorm Dispersa tablets contain sucrose, maltodextrin and aspartame**
These tablets contain sucrose and maltodextrin. Maltodextrin is a form of glucose. Both sucrose and glucose are forms of sugar and may be harmful to your teeth. If you have been told by your doctor
that you have an intolerance to some sugars, contact your doctor before taking these tablets.

These tablets contain aspartame. Aspartame contains a source of phenylalanine which may be harmful to people with phenylketonuria.

3. How to take OxyNorm Dispersa tablets

Always take these tablets 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 many tablets to take and how often.

Do not exceed the dose recommended by your doctor.

Adults (20 years of age and over)
The usual starting dose is one 5 mg tablet 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 tablets, discuss this with your doctor.

Children and adults under 20 years of age
Children and adults under 20 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 you an alternative medicine or a lower dose depending upon your condition.

To remove a tablet from the blister strip:
Diagram 1:
Do not press your tablet through the foil as this may damage it.

Diagram 2:
Detach a pocket containing one tablet from the blister strip by carefully tearing along the perforations.

Diagram 3:
Peel back the corner of the foil where indicated with the arrow and gently remove the tablet.

Place the tablet in your mouth and allow to dissolve before swallowing.

You must only take the tablets by mouth. The tablets should never be crushed and injected as this may lead to serious side effects, which may be fatal.

If you take more OxyNorm Dispersa tablets than you should or if someone accidentally swallows your tablets
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).

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 tablets with you to show to the doctor.

If you forget to take your OxyNorm Dispersa tablets
If you forget to take your tablets, take your next dose as soon as you remember, then go on as before. Do not take two doses within 4 hours. Do not take a double dose to make up for forgotten tablets.

If you stop taking OxyNorm Dispersa tablets
You should not suddenly stop taking these tablets unless your doctor tells you to. If you want to stop taking your tablets, 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 these tablets.

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

4. Possible side effects
Like all medicines, these tablets can cause side effects, although not everybody gets them.

This medicine 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 – a typical hazard of an opioid overdose).

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

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 tablets 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 thoughts or dreams.
• Difficulty in breathing or wheezing, 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 and weakly than expected (respiratory depression).
• Difficulty in swallowing, belching, hiccups, wind, a condition where the small bowel (part of your gut) 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’, hallucinations, mood changes, 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, unusual muscle stiffness or slackness, fainting, reduced consciousness, 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 of the capsules 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 Dispersa’).

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 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.
• Aggression.
• Long term use of OxyNorm 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store OxyNorm Dispersa tablets
Keep this medicine out of the sight and reach of children. Accidental overdose by a child is dangerous and may be fatal.

Do not store above 25°C.
Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month. EXP 08 2020 means that you should not take the tablets after the last day of August 2020.

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 Dispersa tablets contain
The active ingredient is oxycodone hydrochloride. Each tablet contains 5 mg, 10 mg or 20 mg of oxycodone hydrochloride.

The other ingredients are:
- Sucrose
- Maize starch
- Polyacrylate dispersion 30 %
- Hypromellose
- Mannitol
- Silicon dioxide
- Cellulose, microcrystalline
- Crospovidone
- Aspartame
- Spearmint flavour (containing maltodextrin and spearmint oil)
- Magnesium stearate

What OxyNorm Dispersa tablets look like and the contents of the pack
The tablets are white to off-white, round, flat, bevel edged, marked with O on one side and with the strength (5, 10 or 20) on the other.

The tablets are packed in aluminium blister packs with peelable aluminium backing foil and then placed in boxes. In each box there are 14, 28 or 56 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mundipharma Pharmaceuticals Ltd., Millbank House, Arkle Road, Sandyford, Dublin 18, Ireland.

Manufacturer
Mundipharma DC B.V., Leusderend 16, 3832 RC Leusden, The Netherlands.

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 Dispersa
Reference number: PA 1688/6/7
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