Package leaflet: Information for the user

OxyNorm® 10 mg/ml, solution for injection or infusion
Oxycodone hydrochloride

Read all of this leaflet carefully before you start using 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:
1. What OxyNorm injection is and what it is used for
2. What you need to know before you use OxyNorm injection
3. How to use OxyNorm injection
4. Possible side effects
5. How to store OxyNorm injection
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1. What OxyNorm injection is and what it is used for

This injection has been prescribed for you by your doctor to relieve moderate to severe pain. It contains the active ingredient oxycodone which belongs to a group of medicines called strong analgesics or ‘painkillers’.

2. What you need to know before you use OxyNorm injection

Do not use OxyNorm injection if you:
- are allergic (hypersensitive) to oxycodone, or any of the other ingredients of the injection (listed in section 6);
- have breathing problems, such as severe chronic obstructive lung disease, severe bronchial asthma or severe respiratory depression. Your doctor will have told you if you have any of these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- have a condition where the small bowel does not work properly (paralytic ileus) or you have severe pain in your abdomen;
- have a heart problem after long-term lung disease (cor pulmonale);
- have moderate to severe liver problems. If you have other long-term liver problems you should only use this injection if recommended by your doctor;
- have ongoing problems with constipation;
- are under 18 years of age.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before treatment with OxyNorm injection 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);
- have a head injury, severe headache or feel sick as this may indicate that the pressure in your skull is increased;
- have low blood pressure (hypotension);
- have low blood volume (hypovolaemia); this can happen with severe external or internal bleeding, severe burns, excessive sweating, severe diarrhoea or vomiting;
• 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);
• have problems with your gall bladder or bile duct;
• have inflammatory bowel disease;
• 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 which may cause symptoms including weakness, weight loss, dizziness, feeling or being sick), e.g. Addison’s disease;
• have breathing problems such as severe pulmonary disease. Your doctor will have told you if you have this condition. Symptoms may include breathlessness and coughing;
• have kidney or liver problems;
• have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking alcohol or drugs;
• are or have ever been addicted to alcohol or drugs or have a known opioid dependence;
• have an increased sensitivity to pain;
• need to take increasingly higher doses of OxyNorm to gain the same level of pain relief (tolerance).

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.

Other medicines and OxyNorm injection
Concomitant use of opioids and benzodiazepines 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 benzodiazepines or related drugs with opioids the dosage and duration of concomitant treatment should be limited by your doctor.

Please follow your doctor’s dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of sign and symptoms stated above. Contact your doctor when experiencing such symptoms.

Please 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;
• medicines to help you sleep or stay calm (for example hypnotics or sedatives, including benzodiazepines);
• medicines to treat depression (such as paroxetine);
• medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptics);
• 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 (such as ketoconazole, voriconazole, itraconazole and posaconazole);
• antibiotics (such as clarithromycin, erythromycin or telithromycin);
• medicines known as ‘protease inhibitors’ to treat HIV (e.g. boceprevir, ritonavir, indinavir, nelfinavir or saquinavir);
• rifampicin (to treat tuberculosis);
• carbamazepine (a medicine 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.

Using OxyNorm injection with food, drink and alcohol
Drinking alcohol during your treatment with this injection may make you 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 injection.
You should avoid drinking grapefruit juice during your treatment with this medicine.

Pregnancy and breastfeeding
Do not use this injection if you are pregnant or breastfeeding.

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

Driving and using machines
This injection 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 using the injection, or when changing to a higher dose. If you are affected you should not drive or use machinery.

This medicine can affect your ability to drive as it may make you sleepy or dizzy.
• Do not drive while taking this medicine until you know how it affects you.
• It is an offence to drive while you have this medicine in your body over a specified limit unless you have a defence (called the ‘statutory defence’).
• This defence applies when:
  • The medicine has been prescribed to treat a medical or dental problem; and
  • You have taken it according to the instructions given by the prescriber and in the information provided with the medicine.
• Please note that it is still an offence to drive if you are unfit because of the medicine (i.e. your ability to drive is being affected).
Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: https://www.gov.uk/drug-driving-law

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

OxyNorm injection contains less than 1 mmol sodium (23 mg) per 1 ml, i.e. it is essentially “sodium-free”.

3. How to use OxyNorm injection
A doctor or nurse will usually prepare and administer the injection for you. The injection should be used immediately after opening. The dose and how often the injection is given may be adjusted according to the severity of your pain.

Adults (over 18 years of age)
The usual starting dose is dependent upon how the injection is administered. The usual starting doses are as follows:
• As a single injection into a vein, the usual dose is 1 to 10 mg given slowly over 1 to 2 minutes. This can be repeated every 4 hours.
• As an infusion into a vein, the usual starting dose is 2 mg/hour.
• As a single injection through a fine needle into the tissue under the skin, the usual starting dose is 5 mg repeated at 4-hourly intervals if needed.
• As an infusion through a fine needle into the tissue under the skin, the usual starting dose is 7.5 mg/day.
• If given by patient controlled analgesia (PCA), the dose is worked out according to your weight (0.03 mg per kg of body weight). Your doctor or nurse will set a suitable frequency.

**Children**
Children and adolescents under 18 years of age should not be given the injection.

**Patients with kidney or liver problems**
Please tell your doctor if you suffer from kidney or liver problems as they may prescribe a lower dose depending on your condition.

The dose recommended by the doctor should not be exceeded. Check with the doctor or pharmacist if you are unsure.

If you find that you are still in pain whilst being given this injection discuss this with your doctor.

**If you use more OxyNorm injection than you should, or if someone else uses your injection**
Call your doctor or hospital straight away. People who have been given an overdose may feel very sleepy, sick or dizzy. 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 injection with you to show to the doctor.

**If you stop using OxyNorm injection**
You should not suddenly stop using this injection unless your doctor tells you to. If you want to stop using your injection, 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 agitation, anxiety, palpitations, shaking or sweating may occur if you suddenly stop using this injection.

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

**4. Possible side effects**

Like all medicines, this injection 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). **Tell your doctor immediately** if this happens to you.

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

**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 thoughts or dreams.
- Difficulty in breathing or wheezing, shortness of breath, decreased cough reflex.
- Rash.
- Sweating.

Uncommon side effects
(May affect up to 1 in 100 people)
- Difficulty in swallowing, belching, hiccups, wind, a condition where the bowel does not work properly (ileus), inflammation of the stomach, changes in taste.
- A feeling of dizziness or ‘spinning’, hallucinations, mood changes, unpleasant or uncomfortable mood, a feeling of extreme happiness, restlessness, agitation, generally feeling unwell, loss of memory, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness in the hands or feet, seizures, fits or convulsions, blurred vision, fainting, unusual muscle stiffness or slackness, involuntary muscle contractions.
- Difficulty passing urine, impotence, decreased sexual drive, low levels of sex hormones in the blood (‘hypogonadism’, seen in a blood test).
- Fast, irregular heart beat, flushing of the skin.
- Dehydration, thirst, chills, swelling of the hands, ankles or feet.
- Dry skin, severe flaking or peeling of the skin.
- Redness of the face, reduction in size of the pupils in the eye, muscle spasm, high temperature.
- A need to take increasingly higher doses of this medicine to obtain the same level of pain relief (tolerance).
- Colicky abdominal pain or discomfort.
- A worsening of liver function tests (seen in a blood test)

Rare side effects
(May affect up to 1 in 1,000 people)
- Low blood pressure.
- A feeling of ‘faintness’ especially on standing up.
- Hives (nettle rash).

Frequency not known
(Frequency cannot be estimated from the available data)
- An increased sensitivity to pain.
- Aggression.
- Tooth decay.
- Absence of menstrual periods.
- A blockage in the flow of bile from the liver (cholestasis). This can cause itchy skin, yellow skin, very dark urine and very pale stools.
- Long term use of OxyNorm injection 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store OxyNorm injection

Keep this medicine out of the sight and reach of children. Accidental overdose by a child is dangerous and may be fatal.
Do not use this injection after the expiry date which is stated on the ampoule label and carton. EXP 08 2020 means that you should not use the injection after the last day of that month i.e. August 2020. There are no special precautions for storage prior to use however once the ampoule is opened the injection should be used immediately. Any unused portion should be discarded immediately.

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 to protect the environment.

6. **Contents of the pack and other information**

**What OxyNorm injection contains**

The active ingredient is oxycodone hydrochloride.

The other ingredients are:
- Citric acid monohydrate
- Sodium citrate
- Sodium chloride
- Hydrochloric acid, dilute
- Sodium hydroxide
- Water for injections
What OxyNorm injection looks like and the contents of the pack

This injection is a clear, colourless solution supplied in clear glass ampoules. The 10 mg/ml strength is available as either 1 ml or 2 ml of solution (containing 10 mg or 20 mg of oxycodone hydrochloride respectively).

Marketing Authorisation Holder and Manufacturer

This injection is made by Bard Pharmaceuticals Limited for the Marketing Authorisation holder, Napp Pharmaceuticals Limited, both at Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.

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 (free of charge) on:

0800 198 5000

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

Product name: OxyNorm solution for injection or infusion
Reference number: 16950/0128

This leaflet was last revised in January 2018

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