

PACKAGE LEAFLET: INFORMATION FOR THE USER
OxyNorm® 10 mg/ml, solution for injection or infusion
Oxycodone hydrochloride

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 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
6. Contents of the pack and other information

1. What OxyNorm injection is and what it is used for

This medicine has been prescribed for you for the relief of moderate to severe pain. It contains oxycodone which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed for you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be using it for and when it is appropriate to stop, how to do this safely.

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 or have ever been addicted to opioids, alcohol, prescription medicines or illegal drugs;

- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs;
- feel you need to take more tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever;
- 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.

Using this medicine regularly, particularly for a long time, can lead to addiction. Your doctor should have explained how long you will be using it for and when it is appropriate to stop, how to do this safely. Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

Addiction can cause withdrawal symptoms when you stop using this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop using the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Using higher doses or more frequent doses of opioid may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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.

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 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, have recently taken or might take any other medicines, including medicines obtained without a prescription. If you use this injection with some other medicines, the effect of this injection or the other medicines 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;
- 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

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

Pregnancy

Do not use *OxyNorm* injection if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential

harm to the baby. If you use **OxyNorm** injection during pregnancy your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breast-feeding

Do not use **OxyNorm** injection while you are breastfeeding as oxycodone passes into breast milk and will affect your baby.

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).

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.

Your doctor should have discussed with you how long the course of **OxyNorm** injection will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

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

Do not suddenly stop using this medicine. If you want to stop using this medicine discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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.

Drug withdrawal

When you stop using *OxyNorm* injection you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst using *OxyNorm* injection it could be a sign that you have become addicted.

- You need to use the medicine for longer than advised by your prescriber;
- You feel you need to use more than the recommended dose;
- You are using the medicine for reasons other than prescribed;
- When you stop using the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs it is important you talk to your doctor.

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)

- withdrawal symptoms (see section 'Drug withdrawal');
- 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)

- dependence and addiction (see section 'How do I know if I am addicted?');
- 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.

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

Manufacturer:

BBraun Melsungen AG
Mistelweg 2, Berlin, D-12357, Germany

Marketing Authorisation Holder :

Napp Pharmaceuticals Limited,
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