

OxyNorm[®] 5mg Capsules/OxyNorm[®] 10mg Capsules/OxyNorm[®] 20mg Capsules

(oxycodone hydrochloride)

Patient Information Leaflet

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.

Your medicine is called OxyNorm 5mg, 10mg and 20mg capsules but will be referred to as OxyNorm capsules throughout this leaflet.

What is in this leaflet

- 1 What OxyNorm capsules are and what they are 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 they are used for

These capsules have been prescribed for you by your doctor to relieve moderate to severe pain. They contain the active ingredient oxycodone which belongs to a group of medicines called strong analgesics or 'painkillers'.

2 What you need to know before you take OxyNorm capsules

Do not take OxyNorm capsules if you:

- * are allergic to oxycodone, or any of the other ingredients of the capsules (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), your stomach empties more slowly than it should (delayed gastric emptying) 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 take these capsules if recommended by your doctor;
- * have ongoing problems with constipation;
- * are under 18 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking these capsules 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 these tablets.

Other medicines and OxyNorm capsules

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 take these capsules with some other medicines, the effect of these capsules 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;
- * medicines to help you sleep or stay calm (for example tranquillisers, hypnotics or sedatives);
- * medicines to treat depression (such as paroxetine);
- * medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptic drugs);
- * 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 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 capsules with food, drink and alcohol

Drinking alcohol during your treatment with these capsules 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 capsules.

You should avoid drinking grapefruit juice during your treatment with this medicine.

Pregnancy and breastfeeding

Do not take these capsules if you are pregnant or breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

These capsules may cause a number of side effects such as drowsiness which may 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 capsules, 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-drivinglaw>

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

OxyNorm 5 mg capsules contain sunset yellow (E110)

The 5 mg capsules contain sunset yellow (E110) which may cause allergic reactions.

3 How to take OxyNorm capsules

Always take these capsules exactly as your doctor has told you. The label on your medicine will tell you how many capsules to take and how often.

Adults (over 18 years of age)

The usual starting dose is one 5 mg capsule 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 capsules, discuss this with your doctor.

Children

Children and adolescents under 18 years of age should not take the capsules.

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.

OxyNorm[®] 5mg Capsules/OxyNorm[®] 10mg Capsules/OxyNorm[®] 20mg Capsules

(oxycodone hydrochloride)

Patient Information Leaflet (continued)

Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure.

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

You must only take the capsules by mouth. The capsules 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 or if someone accidentally swallows your capsules

Call your doctor or hospital straight away. People who have taken 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 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 forgotten capsules.

If you stop taking OxyNorm capsules

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

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

4 Possible side effects

Like all medicines, these capsules 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 these capsules.

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 capsules 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, seizures, fits or convulsions, blurred vision, fainting, unusual muscle stiffness or slackness, involuntary muscle contractions.
- * Difficulty in 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 the capsules 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 capsules during pregnancy may cause lifethreatening 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.

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

5 How to store OxyNorm capsules

- * Do not store above 30°C.
- * KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- * Do not use this medicine after the expiry date shown on the carton or blister strip. If your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal.

6 Contents of the pack and other information

What this medicine contains

The capsules contains the active ingredient oxycodone.

Each hard capsule contains 5mg of Oxycodone hydrochloride, equivalent to 4.5mg Oxycodone.

Each hard capsule contains 10mg of Oxycodone hydrochloride, equivalent to 9mg Oxycodone.

Each hard capsule contains 20mg of Oxycodone hydrochloride, equivalent to 18mg Oxycodone.

The following inactive ingredients are also included in OxyNorm capsules, Microcrystalline cellulose, Magnesium stearate, Titanium oxide E171, Red iron oxide E172, Yellow iron oxide E172, Indigo carmine E132, Sodium lauryl sulphate, Gelatin and black printing ink.

In addition, the 5 mg capsule contains sunset yellow E110

What this medicine looks like and contents of the pack

OxyNorm 5mg are a orange/beige coloured hard capsules, with '5' printed on the body and 'ONR' on the cap, each capsule contains a white powder.

OxyNorm 10mg are a white/beige coloured hard capsules, with '10' printed on the body and 'ONR' on the cap, each capsule contains a white powder.

OxyNorm 20mg are a pink/beige coloured hard capsules, with '20' printed on the body and 'ONR' on the cap each capsule contains a white powder.

The capsules are available in blister packs of 14's & 56's.

Manufacturer and Licence Holder

The capsules are manufactured by Bard Pharmaceuticals Limited, Cambridge Science Park, Cambridge, CB4 0GW, United Kingdom and are procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

POM	PL Number: 15184/1179 OxyNorm 5mg Capsules
	PL Number: 15184/1180 OxyNorm 10mg Capsules
	PL Number: 15184/1181 OxyNorm 20mg Capsules

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited, Tel: 01527 505414

for help.

Oxycodone Hydrochloride 5mg Capsules/Oxycodone Hydrochloride 10mg Capsules/Oxycodone Hydrochloride 20mg Capsules

Patient Information Leaflet

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.

Your medicine is called OxyNorm 5mg, 10mg and 20mg Capsules but will be referred to as Oxycodone Hydrochloride capsules throughout this leaflet.

What is in this leaflet

- 1 What Oxycodone Hydrochloride capsules are and what they are used for
- 2 What you need to know before you take Oxycodone Hydrochloride capsules
- 3 How to take Oxycodone Hydrochloride capsules
- 4 Possible side effects
- 5 How to store Oxycodone Hydrochloride capsules
- 6 Contents of the pack and other information

1 What Oxycodone Hydrochloride capsules are and what they are used for

These capsules have been prescribed for you by your doctor to relieve moderate to severe pain. They contain the active ingredient oxycodone which belongs to a group of medicines called strong analgesics or 'painkillers'.

2 What you need to know before you take Oxycodone Hydrochloride capsules

Do not take Oxycodone Hydrochloride capsules if you:

- * are allergic to oxycodone, or any of the other ingredients of the capsules (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), your stomach empties more slowly than it should (delayed gastric emptying) 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 take these capsules if recommended by your doctor;
- * have ongoing problems with constipation;
- * are under 18 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking these capsules 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 Oxycodone 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 these tablets.

Other medicines and Oxycodone Hydrochloride capsules

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 take these capsules with some other medicines, the effect of these capsules 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;
- * medicines to help you sleep or stay calm (for example tranquillisers, hypnotics or sedatives);
- * medicines to treat depression (such as paroxetine);
- * medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptic drugs);
- * 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 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 Oxycodone Hydrochloride capsules with food, drink and alcohol

Drinking alcohol during your treatment with these capsules 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 Oxycodone Hydrochloride capsules.

You should avoid drinking grapefruit juice during your treatment with this medicine.

Pregnancy and breastfeeding

Do not take these capsules if you are pregnant or breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

These capsules may cause a number of side effects such as drowsiness which may 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 capsules, 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-drivinglaw>

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

Oxycodone 5 mg capsules contain sunset yellow (E110)

The 5 mg capsules contain sunset yellow (E110) which may cause allergic reactions.

3 How to take Oxycodone Hydrochloride capsules

Always take these capsules exactly as your doctor has told you. The label on your medicine will tell you how many capsules to take and how often.

Adults (over 18 years of age)

The usual starting dose is one 5 mg capsule 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 capsules, discuss this with your doctor.

Children

Children and adolescents under 18 years of age should not take the capsules.

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.

Oxycodone Hydrochloride 5mg Capsules/Oxycodone Hydrochloride 10mg Capsules/Oxycodone Hydrochloride 20mg Capsules

Patient Information Leaflet (continued)

Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure.

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

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

If you take more Oxycodone Hydrochloride capsules than you should or if someone accidentally swallows your capsules

Call your doctor or hospital straight away. People who have taken 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 capsules with you to show to the doctor.

If you forget to take Oxycodone Hydrochloride 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 forgotten capsules.

If you stop taking Oxycodone Hydrochloride capsules

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

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

4 Possible side effects

Like all medicines, these capsules 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 these capsules.

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 capsules 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, seizures, fits or convulsions, blurred vision, fainting, unusual muscle stiffness or slackness, involuntary muscle contractions.
- * Difficulty in 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 the capsules 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 capsules during pregnancy may cause lifethreatening 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.

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

5 How to store Oxycodone Hydrochloride capsules

- * Do not store above 30°C.
- * KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- * Do not use this medicine after the expiry date shown on the carton or blister strip. If your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal.

6 Contents of the pack and other information

What this medicine contains

The capsules contains the active ingredient oxycodone.

Each hard capsule contains 5mg of Oxycodone hydrochloride, equivalent to 4.5mg Oxycodone.

Each hard capsule contains 10mg of Oxycodone hydrochloride, equivalent to 9mg Oxycodone.

Each hard capsule contains 20mg of Oxycodone hydrochloride, equivalent to 18mg Oxycodone.

The following inactive ingredients are also included in Oxycodone Hydrochloride capsules, Microcrystalline cellulose, Magnesium stearate, Titanium oxide E171, Red iron oxide E172, Yellow iron oxide E172, Indigo carmine E132, Sodium lauryl sulphate, Gelatin and black printing ink.

In addition, the 5 mg capsule contains sunset yellow E110

What this medicine looks like and contents of the pack

Oxycodone Hydrochloride 5mg are a orange/beige coloured hard capsules, with '5' printed on the body and 'ONR' on the cap, each capsule contains a white powder. Oxycodone Hydrochloride 10mg are a white/beige coloured hard capsules, with '10' printed on the body and 'ONR' on the cap, each capsule contains a white powder.

Oxycodone Hydrochloride 20mg are a pink/beige coloured hard capsules, with '20' printed on the body and 'ONR' on the cap each capsule contains a white powder.

The capsules are available in blister packs of 14's & 56's.

Manufacturer and Licence Holder

The capsules are manufactured by Bard Pharmaceuticals Limited, Cambridge Science Park, Cambridge, CB4 0GW, United Kingdom and are procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

POM	PL Number: 15184/1179 Oxycodone Hydrochloride 5mg Capsules
	PL Number: 15184/1180 Oxycodone Hydrochloride 10mg Capsules
	PL Number: 15184/1181 Oxycodone Hydrochloride 20mg Capsules

Revision date: 26/04/16

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