

PACKAGE LEAFLET: INFORMATION FOR THE USER

Oxycodone hydrochloride 1 mg/ml oral solution
Oxycodone hydrochloride 10 mg/ml oral solution

(referred to as Oxycodone oral solution in this leaflet)
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 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 Oxycodone oral solution is and what it is used for
2. What you need to know before you take Oxycodone oral solution
3. How to take Oxycodone oral solution
4. Possible side effects
5. How to store Oxycodone oral solution
6. Contents of the pack and other information

1. What Oxycodone oral solution is and what it is used for

Oxycodone oral solution contains the active substance oxycodone hydrochloride, which belongs to a group of medicines called strong opioids and has a powerful analgesic effect.

This medicine is used to relieve severe pain such as cancer pain.

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 taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Oxycodone oral solution

Do not take Oxycodone oral solution if you:

- are allergic to oxycodone or any of the other ingredients of this medicine (listed in section 6).
- have severe breathing problems, severely reduced breathing with low oxygen in the blood (hypoxia) and/or too much carbon dioxide (hypercapnia) in the blood;
- have severe chronic obstructive lung disease, pulmonary heart disease (cor pulmonale) or severe bronchial asthma.
- have a condition where the small bowel does not work properly (intestinal loop, paralytic ileus), making your stomach emptying more slowly than it should (delayed gastric emptying)

Warnings and precautions

Talk to your doctor or pharmacist before taking Oxycodone oral solution. Never stop treatment with Oxycodone oral solution without talking to your doctor.

Your doctor will closely monitor you and adjust your treatment if you:

- are elderly;
- have a reduced general condition;
- have a head injury, severe (due to risk of increased pressure in the brain);
- have low blood pressure (hypotension);
- have poor kidney function;
- have impaired liver function;
- have an under or overactive thyroid gland (hypothyroidism or hyperthyroidism);
- have myxoedema (a thyroid disorder with dryness, coldness and swelling ('puffiness') of the skin affecting the face and limbs
- have poor adrenal gland function (your adrenal gland is not working properly), e.g. Addison's disease;
- have an enlarged prostate gland (prostate hypertrophy), which causes difficulty in passing urine (in men);
- have disturbed perception of reality as a result of overdose with another drug (toxic psychosis);
- have impaired lung function;
- have inflammation of the pancreas (pancreatitis);
- have biliary tract diseases;
- have a chronic inflammation of the intestine (inflammatory bowel disease);
- have low blood volume (hypovolaemia);
- taking a type of medicine to treat anxiety or insomnia called benzodiazepines, or other medicines that may reduce your brain activity (eg medicines to treat nausea, insomnia, mental disorders, allergies, severe pain or anaesthetics)
- treated or have been treated for depression (MAO inhibitors) in the last two weeks.
- 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

Other medicines and Oxycodone oral solution

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

Concomitant use of opioids and other sedatives like 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.

Repeated long term use of Oxycodone oral solution may lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Oxycodone oral solution, it is important that you consult your doctor.

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

Oxycodone may cause breathing difficulties or aggravate pre-existing breathing difficulties during sleep. These difficulties may include breathing pauses during sleep, waking up due to shortness of breath, difficulty staying asleep or pronounced sleepiness during the day. Contact your doctor if you or anyone else observes these symptoms. Your doctor may want to reduce your dose.

Oxycodone Hydrochloride can inhibit the cough reflex. Oxycodone oral solution is addictive. You can get a so-called withdrawal syndrome when treatment with Oxycodone Hydrochloride is stopped abruptly.

Sudden discontinuation of treatment may cause the following withdrawal symptoms:

- restlessness
- watery eyes
- runny nose
- sweating
- restless sleep
- uncontrolled movements
- anxiety
- cramps.

These symptoms may worsen over the next three days. The dose should be reduced gradually to avoid withdrawal symptoms.

Prolonged use may result in the risk of losing the effect of Oxycodone oral solution. You will then need gradually higher doses to maintain pain control. Your doctor will consider whether it may be necessary to reduce the dose or switch to another similar medicine.

Sleep-related breathing disorders

Oxycodone oral solution 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.

Children and adolescents

Oxycodone oral solution should not be given to children and adolescents under 18 years of age, as experience in treating these patient groups is lacking.

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The risk of side effects increases if you use antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine) known as Selective Serotonin Re-uptake Inhibitors (SSRIs) or Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) which can cause a condition known as serotonin toxicity. 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 if you are experiencing such symptoms.

Tell your doctor about all sedatives you use and follow your doctor's dosage carefully. It can be helpful to make friends and relatives aware of the signs and symptoms mentioned above.

Tell your doctor or pharmacist if you are taking: so-called MAO inhibitors (used to treat depression,

Parkinson's disease or others diseases). Your doctor will closely monitor you and adjust your treatment with Oxycodone oral solution. This also applies if you just have discontinued treatment with MAO inhibitors.

medicines to help you sleep or stay calm (for example sleeping pills, anxiolytics and sedatives, including benzodiazepines)

medicines used to treat depression (such as paroxetine) medicines used to treat psychiatric or mental disorders (such as phenothiazines or neuroleptic drugs)

other strong analgesics ("painkillers") medicines to treat epilepsy, pain and anxiety (gabapentin and pregabalin)

medicines to treat allergies, motion sickness or nausea Oxycodone Hydrochloride at the same time as medicines that reduce the blood's ability to coagulate (so-called coumarin derivatives), coagulation time can increase or decrease. Your doctor may also need to adjust the dose of Oxycodone oral solution.

The following medicines may increase the effect of Oxycodone oral solution

- antibiotics (such as clarithromycin, erythromycin or telithromycin)
- antifungal medicines (such as ketoconazole, voriconazole, itraconazole and posaconazole)
- medicines to treat HIV known as protease inhibitors, such as boceprevir, ritonavir, indinavir, nelfinavir or saquinavir
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn)

Your doctor will consider whether a dose reduction is necessary.

The following medicines may reduce the effect of Oxycodone oral solution

- 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)

Your doctor will consider whether an increase in dose is necessary.

Oxycodone oral solution with food, drink and alcohol

You can take oxycodone hydrochloride oral solution with food, but it is not necessary.

You should not drink alcohol while you are taking Oxycodone oral solution.

Drinking alcohol during your treatment with this medicine 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.

You should avoid drinking grapefruit juice during your treatment with Oxycodone oral solution, since this can increase the effect of the medicine.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Do not take Oxycodone oral solution unless you have discussed this with your doctor and the benefits of

treatment outweigh the potential harm to the baby.

The use of Oxycodone oral solution should be avoided as much as possible during pregnancy. Using Oxycodone Hydrochloride in the latter part of your pregnancy may cause withdrawal symptoms in the newborn. Use of Oxycodone oral solution during birth can cause severe breathing problems in the newborn. Long-term use of Oxycodone oral solution during pregnancy may cause life-threatening withdrawal symptoms in the newborn. Symptoms to be seen after in the newborn are irritability, hyperactivity and abnormal sleep patterns, loud crying, trembling, vomiting, diarrhoea and lack of weight gain. Oxycodone oral solution should not be used during breast-feeding, as it passes into the breast milk. Use of this medicine during breast-feeding may cause breathing problems in breast-fed infants.

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 more noticeable when you first start taking this medicine, 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: <http://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.

Oxycodone oral solution contains sodium and sodium benzoate (E 211)

This medicine contains less than 1 ml sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

This medicine contains 1 mg sodium benzoate in each ml, which may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Oxycodone oral solution 10 mg/ml oral solution contains sunset yellow (E 110)

This medicine also contains sunset yellow (E 110), which may cause allergic reactions

3. How to take Oxycodone oral solution

Always take this medicine exactly as your doctor has told you. Contact a doctor or pharmacist if you are not sure.

Use in adults

Your doctor will prescribe the dose required to treat your pain. If you find that you are still in pain whilst taking this medicine discuss this with your doctor.

1 mg/ml
The usual starting dose is 5 ml (equivalent to 5 mg oxycodone hydrochloride) every 6 hours.

10 mg/ml

The usual starting dose is 0.5 ml (equivalent to 5 mg oxycodone hydrochloride) every 6 hours.

The daily dose and any dose adjustments during treatment are determined by the doctor treating you and depend on the past dosage. Patients who have previously taken opioids may, due to their experience with opioid treatment, start treatment with higher doses.

The doctor may prescribe a lower starting dose if you are elderly or if you have impaired renal function and/or impaired hepatic function.

You must only take this medicine by mouth. This medicine should never be injected as this may lead to serious side effects, which may be fatal.

If you take more Oxycodone hydrochloride oral solution than you should

Call your doctor or hospital straight away if you have taken too much of Oxycodone oral solution, or if a child by accident has ingested Oxycodone oral solution. The following symptoms may occur with overdose:

- pin-sized pupils
- breathing difficulties
- drowsiness
- muscle weakness
- Pulmonary edema
- slow pulse
- drop in blood pressure.

In severe cases, coma and unconsciousness may occur. When seeking medical attention make sure that you take this leaflet and any remaining medicine with you to show to the doctor.

If you forget to take Oxycodone oral solution

If you miss a dose you should take the next dose as soon as you remember, but if there is a short time left until the next dose, then you should skip the missed dose. Then you can carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Oxycodone oral solution

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. The doctor will tell you how to do this, usually by reducing the dose gradually so that the risk of experiencing withdrawal symptoms is reduced. Withdrawal symptoms such as restlessness, anxiety, insomnia, involuntary muscle contractions, shaking, sweating or gastro intestinal problems 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.

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.**

Nausea or vomiting is usually transient and can be relieved with antiemetics. As with other strong opioids, constipation can occur and can be treated with laxatives. If these side effects persist, they should be investigated for alternative causes.

Other possible side effects

Very common (may affect more than 1 in 10 people):
- Constipation

- Nausea
- Vomiting
- Drowsiness
- Dizziness
- Headache
- Itchy skin

Common (may affect up to 1 in 10 people):

- Decreased appetite
- Anxiety, depression, difficulty in sleeping, nervousness, abnormal thoughts or dreams and confusion
- Shaking (tremor), lack of energy
- Shortness of breath
- Abdominal pain, diarrhoea, dry mouth, indigestion
- Rash, excessive sweating
- A feeling of unusual weakness, tiredness

Uncommon (may affect up to 1 in 100 people):

- Hypersensitivity
- Dehydration
- Difficulty in swallowing, flatulence, ileus (a condition where the bowel does not work properly), acid reflux
- A feeling of dizziness or 'spinning', hallucinations, mood changes, restlessness, agitation
- Loss of memory, difficulty in speaking, alteration in the perception of taste, tingling of the skin, 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')
- Fast, irregular heart beat
- Dilated blood vessels
- Slow or weak breathing (respiratory depression)
- Thirst, chills, swelling of the hands, ankles or feet (oedema)
- Dry skin
- Reduction in size of the pupils in the eye, visual impairment
- A need to take increasingly higher doses of this medicine to obtain the same level of pain relief (tolerance)
- Drug addiction
- Drug withdrawal syndrome
- Feeling of sickness
- A worsening of liver function tests (seen in a blood test)

Rare (may affect up to 1 in 1,000 people):

- Low blood pressure.
- A feeling of faintness' especially on standing up.
- Hives (nettle rash).

Not known (may affect an unknown number of people):

- Severe allergic reaction (anaphylaxis)
- An increased sensitivity to pain.
- Aggression.
- Sleep apnea syndrome (difficulties in breathing during sleep)
- Tooth decay.
- Absence of menstrual periods.
- Biliary colic
- A blockage in the flow of bile from the liver to the intestines (cholestasis)
- Withdrawal symptoms in the newborns
- Sleep apnoea (breathing pauses during sleep)

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 the package 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 Oxycodone oral solution

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and bottle-label after "EXP". The expiry date refers to the last day of that month. Use within 30 days of opening.

This medicine does not require any special storage conditions.

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 Oxycodone oral solution contains

The active substance is oxycodone hydrochloride.

Each ml of 1 mg/ml oral solution contains 1 mg oxycodone hydrochloride equivalent to 0.9 mg oxycodone.

Each ml of 10 mg/ml oral solution contains 10 mg oxycodone hydrochloride equivalent to 9 mg oxycodone.

The other ingredients are saccharin sodium, sodium benzoate (E 211), citric acid monohydrate, sodium citrate, hydrochloric acid, sodium hydroxide, purified water, hypromellose (Oxycodone 1 mg/ml oral solution), sunset yellow FCF (E 110) (Oxycodone Hydrochloride 10 mg/ml oral solution).

What Oxycodone oral solution looks like and contents of the pack

Oxycodone hydrochloride oral solution 1 mg/ml oral solution is a clear colourless/straw-coloured solution. Each bottle contains 250 ml solution.

Oxycodone hydrochloride oral solution 10 mg/ml oral solution is a clear orange solution. Each bottle contains 120 ml solution. A 2 ml oral syringe is also supplied

Marketing Authorisation Holder and Manufacturer

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

United Kingdom (NI): Oxycodone Hydrochloride 1 mg/ml and 10 mg/ml oral solution
Norway :Oxycodone Ethypharm 1mg/ml and 10 mg/ml mikstur, opløsning

This leaflet was last revised on 03/2022

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