



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 10mg/ml Solution contains sodium
This medicine contains 0.85mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.04% of the recommended maximum daily dietary intake of sodium for an adult.

Oxycodone 10mg/ml Solution contains sunset yellow (E110)
This medicine contains sunset yellow (E110), which may cause allergic reactions.

Oxycodone 10mg/ml Solution contains sodium benzoate (E211)
This medicine contains 1mg sodium benzoate in each ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Oxycodone 10mg/ml Solution

Always take this medicine exactly as your doctor has told you. The label on your medicine will tell you how much to take and how often. Your doctor should have discussed with you how long the course of Oxycodone 10mg/ml Solution will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Oxycodone 10mg/ml Solution, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also if you stop using Oxycodone 10mg/ml Solution).

Adults (over 18 years of age)
The usual starting dose is 0.5ml every four to six hours. However, 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.

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

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

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 10mg/ml Solution than you should or if someone accidentally swallows your medicine
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 medicine with you to show the doctor. An overdose may result in a brain disorder (known as toxic leukoencephalopathy).

If you forget to take Oxycodone 10mg/ml Solution
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 four hours. Do not take a double dose to make up for a forgotten dose.

If you stop taking Oxycodone 10mg/ml Solution
Do not suddenly stop taking this medicine. If you want to stop taking 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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 medicine.

Drug withdrawal
When you stop taking Oxycodone 10mg/ml Solution 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 taking Oxycodone 10mg/ml Solution it could be a sign that you have become addicted.

- You need to take 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 taking 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, 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 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
Sleep apnoea (breathing pauses during sleep)
Long term use of Oxycodone 10mg/ml Solution 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
A problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction).

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, website: 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 10mg/ml Solution

Keep this medicine out of the sight and reach of children. Accidental overdose by a child is dangerous and may be fatal. Store this medicine in a locked safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

- Do not store above 25°C
Store in the original package in order to protect from light
Do not use after the expiry date (shown as Exp. On the packaging). The expiry date refers to the last day of the month, your doctor or nurse will check for this
Once opened this medicine must be used within 1 month
Consult a pharmacist if signs of deterioration of the product are observed.

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 10mg/ml Solution contains
The active ingredient is oxycodone hydrochloride. Each 1ml contains oxycodone hydrochloride 10mg (equivalent to 9mg oxycodone base).

The other ingredients are: citric acid monohydrate, sodium citrate, sodium benzoate (E211), sodium saccharin, sunset yellow (E110) and purified water.

What Oxycodone 10mg/ml Solution looks like and the contents of the pack
This medicine is a clear orange solution. Each bottle contains 120ml of solution.

Marketing Authorisation Holder:
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK
Manufacturer:
CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK
Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only). Please be ready to give the following information:

Table with 2 columns: Product name, Reference number. Row 1: Oxycodone Hydrochloride 10mg/ml Oral Solution, 29831/0459

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in 01/2024

