

Package leaflet: Information for the user

Oxeltra 5mg, 10mg, 15mg, 20mg, 30mg, 40mg, 60mg and 80mg Prolonged-Release Tablets 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 Oxeltra tablets are and what they are used for
2. What you need to know before you take Oxeltra tablets
3. How to take Oxeltra tablets
4. Possible side effects
5. How to store Oxeltra tablets
6. Contents of the pack and other information

1. What Oxeltra tablets are and what they are used for

This medicine has been prescribed for you for the relief of moderate to severe pain over a period of 12 hours. It contains the active ingredient 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 taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Oxeltra tablets

Do not take Oxeltra tablets if you:

- are allergic (hypersensitive) to oxycodone, or any of the other ingredients of this medicine (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 increased carbon dioxide levels in the blood. Symptoms may include dizziness, drowsiness, fatigue, shortness of breath and headache
- have moderate to severe liver problems. If you have other long-term liver problems you should only take these tablets if recommended by your doctor
- have ongoing problems with constipation
- have a rare hereditary problem of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption
- are under 18 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- or anyone in your family 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 of Oxeltra 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)
- know you are suffering from a brain injury or tumour, or you 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
- feel very lightheaded or faint
- 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 severely impaired lung function. Symptoms may include breathlessness and coughing
- have long term pain unrelated to cancer
- have a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea
- have liver or kidney problems.

Do not use Oxeltra tablets for acute post-operative pain because of the increased risk of dependency and developing serious breathing problems.

If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital if you are taking Oxeltra tablets. Your doctor may adjust your dose.

You may experience hormonal changes while taking these tablets. Your doctor may want to monitor these changes.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Sleep-related breathing disorders

Oxeltra tablets 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.

Tolerance, dependence and addiction

This medicine contains oxycodone, which is an opioid. It can cause dependence and/or addiction.

This medicine contains oxycodone which is an opioid drug. Repeated use of oxycodone painkillers can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Oxeltra tablets can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

If you have concerns that you may become dependent on Oxeltra tablets it is important that you consult your doctor. 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.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it. You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.

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.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Oxeltra tablets if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction")
- You are a smoker
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Oxeltra tablets, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects').

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

Withdrawal

Addiction can cause withdrawal symptoms when you stop taking 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. If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3), If you stop taking Oxeltra tablets).

It is important that you do not stop taking 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. Taking higher doses or more frequent doses of opioid may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Do not inject Oxeltra tablets. This can cause serious side effects including tissue death at the site of injection, inflammation of the lungs and damage to the heart which may be fatal.

Other medicines and Oxeltra tablets

Taking Oxeltra tablets at the same time as other medicines that slow down the central nervous system can cause slow or difficulty breathing (respiratory depression), severe sleepiness, loss of consciousness and death. These medicines include:

- other medicines used to treat pain known as opioids (such as codeine or morphine)
- medicines used to treat epilepsy (gabapentinoids) such as pregabalin
- medicines used to treat anxiety
- medicines used to make you feel sleepy (such as benzodiazepines)
- medicines used to treat psychiatric or mental disorders (such as phenothiazines)
- anaesthetics
- muscle relaxants
- medicines used to treat high blood pressure
- a type of medicine used to treat depression known as monoamine oxidase inhibitors (MAOIs), such as tranylcypromine, phenelzine and isocarboxazid. You should not take Oxeltra tablets if you are currently taking this type of medicine, or have taken this medicine in the last two weeks.

Because of this, your doctor will only prescribe Oxeltra tablets where there are no other treatment options, and only in small doses for short periods of time. If you or your friends, family or caregivers notice that you are having difficulty breathing or that you have become very sleepy or lost consciousness you (or they) should inform your doctor **immediately**.

Taking Oxeltra tablets with medicines used to treat depression known as Selective Serotonin Re-uptake Inhibitors (SSRIs) or Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) can cause a condition known as serotonin toxicity. The symptoms of this include agitation, seeing or hearing things that aren't real (hallucinations), loss of consciousness, a fast heartbeat, blood pressure changes, increased body temperature, muscle twitching, lack of coordination, stiffness, feeling or being sick, or diarrhoea. If you are taking SSRI or SNRI medicines such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline or venlafaxine your doctor may reduce your dose of Oxeltra tablets.

Tell your doctor or pharmacist if you are taking any of the following medicines, as they may need to adjust your dose:

- a type of medicine used to treat depression known as tricyclic antidepressants, such as amitriptyline, clomipramine, imipramine, lofepramine or nortriptyline
- medicines used to treat allergies such as cetirizine, fexofenadine or chlorphenamine
- quinidine (a medicine to treat an irregular 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)
- medicines used to treat seizures, fits or convulsions such as carbamazepine and phenytoin
- a herbal remedy called St John's Wort (also known as *Hypericum perforatum*)
- medicines to treat Parkinson's disease.

Taking Oxeltra tablets with food, drink and alcohol

Drinking alcohol whilst taking Oxeltra tablets may make you feel more 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 Oxeltra tablets.

You should avoid drinking grapefruit juice while you are taking these tablets.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take Oxeltra 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 Oxeltra during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breast-feeding

Do not take Oxeltra while you are breastfeeding as oxycodone passes into breast milk and will affect your baby..

Driving and using machines

These tablets may cause a number of side effects such as drowsiness or dizziness which could affect your ability to drive or use machinery (see section 4 'Possible side effects' for a full list of side effects). These are usually most noticeable when you first start taking the tablets, or when changing to a higher dose.

- Do not drive while taking this medicine until you know how it affects you
- It is an offence to drive if this medicine affects your ability to drive
- However you would not be committing an offence if:
 - 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 or in the information provided with the medicine and
 - It was not affecting your ability to drive safely.

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

Oxeltra tablets contain lactose

These tablets contain lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

3. How to take Oxeltra tablets

Always take these tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your prescriber should have discussed with you how long the course of tablets 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 Oxeltra tablets 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 Oxeltra tablets).

Adults (over 18 years of age)

The usual starting dose is one 10mg tablet every 12 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 tablets, discuss this with your doctor.

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

Swallow your tablets whole with water. **Do not crush, dissolve or chew them.**

Oxeltra tablets are designed to work properly over 12 hours when swallowed whole. If a tablet is broken, crushed, dissolved or chewed, the entire 12-hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an overdose, which may be fatal.

You should take your tablets every 12 hours. For instance, if you take a tablet at 8 o'clock in the morning, you should take your next tablet at 8 o'clock in the evening.

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

Children

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

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.

If you take more Oxeltra tablets than you should or if someone accidentally swallows your tablets

Call your doctor or hospital **immediately**. People who have taken an overdose may feel very sleepy, sick or dizzy, or have hallucinations. 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 tablets with you to show to the doctor. An overdose may result in a brain disorder (known as toxic leukoencephalopathy).

If you forget to take your Oxeltra tablets

If you remember within 4 hours of the time your tablet was due, take your tablet straight away. Take your next tablet at your normal time. If you are more than 4 hours late, please call your doctor or pharmacist for advice. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Oxeltra tablets

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber 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, these tablets 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. These may be signs of a serious allergic reaction.

The most serious side effect is a condition where you breathe more slowly or weakly than usual (respiratory depression) and can lead to severe sleepiness and loss of consciousness. This side effect may affect up to 1 in 100 people and is more likely to occur when taking certain other medicines (see section 2 'Other medicines and Oxeltra tablets'). **Tell your doctor immediately** if this happens to you. You may wish to ask friends, family or caregivers to monitor you for these signs and symptoms.

Drug Withdrawal

When you stop taking Oxeltra, 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.

Other possible side effects

Very common (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 (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 (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 or unpleasant taste
- a feeling of dizziness or spinning (vertigo), hallucinations, mood changes, extreme happiness, disorientable, 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

- or impaired vision unusual muscle stiffness or slackness, involuntary muscle contractions or spasms
- difficulty or pain in passing urine, impotence, decreased sexual drive, low levels of sex hormones in the blood ('hypogonadism', seen in a blood test)
- fast, irregular heartbeat, palpitations, a feeling of lightheadedness, dizziness or fainting, 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, high temperature
- colicky abdominal pain or discomfort
- a worsening of liver function tests (seen in a blood test).

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

- low blood pressure or feeling faint, especially on standing up
- a raised, itchy rash (hives).

Frequency not known (frequency cannot be estimated from the available data)

- dependence and addiction (see section "How do I know if I am addicted?" in section 2 of the leaflet)
- withdrawal symptoms (see 'Drug withdrawal' in section 2 of the leaflet)
- a need to take increasingly higher doses of this medicine to obtain the same level of pain relief (tolerance)
- an increased sensitivity to pain
- aggression
- tooth decay
- absence of menstrual periods
- a problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction)
- 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 Oxeltra tablets 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.

You may see the remains of the tablets in your faeces. This should not affect how the tablets work.

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 <http://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 Oxeltra tablets

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 use any tablets after the expiry date which is stated on the blister and carton or bottle label. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not take your tablets if they are broken or crushed as this can be dangerous and can cause serious problems such as overdose.

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 Oxeltra tablets contain

The active ingredient is oxycodone hydrochloride. Each tablet contains 5mg, 10mg, 15mg, 20mg, 30mg, 40mg, 60mg or 80mg of oxycodone hydrochloride.

The other ingredients are: lactose monohydrate, hypromellose (E464), povidone, stearic acid, magnesium stearate and anhydrous silica colloidal.

In addition, the tablet coatings contain the following:

- 5mg – polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b), indigo carmine aluminium lake (E132) and iron oxide yellow (E172).
- 10mg – hypromellose (E464), titanium dioxide (E171), macrogol (E1521) and polysorbate (E433).
- 15mg – polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b), iron oxide black (E172) and iron oxide yellow (E172).
- 20mg – polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b) and iron oxide red (E172).
- 30mg – polyvinyl alcohol (E1203), macrogol (E1521), talc (E553b), iron oxide red (E172), iron oxide black (E172) and indigo carmine aluminium lake (E132).
- 40mg – polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b) and iron oxide yellow (E172).
- 60mg – polyvinyl alcohol (E1203), macrogol (E1521), talc (E553b), iron oxide red (E172), carmine and iron oxide black (E172).
- 80mg – polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b), indigo carmine aluminium lake (E132) and iron oxide yellow (E172).

What Oxeltra tablets look like and the contents of the pack

The tablets are marked OX along with the strength (5, 10, etc) on one side. All strengths are round, bi-convex, film coated tablets.

The tablets are all film coated in the following colours: 5mg - blue, 10mg - white, 15mg - grey, 20mg - pink, 30mg - brown, 40mg - yellow, 60mg - red, 80mg - green.

Oxeltra 5mg Tablets are available in cartons containing 28 or 100 tablets.

Oxeltra 10mg, 15mg, 20mg, 30mg, 40mg, 60mg and 80mg Tablets are available in cartons containing 56 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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:

Product name	Reference number
Oxeltra 5mg Prolonged-Release Tablets	29831/0630
Oxeltra 10mg Prolonged-Release Tablets	29831/0631
Oxeltra 15mg Prolonged-Release Tablets	29831/0632
Oxeltra 20mg Prolonged-Release Tablets	29831/0633
Oxeltra 30mg Prolonged-Release Tablets	29831/0634
Oxeltra 40mg Prolonged-Release Tablets	29831/0635
Oxeltra 60mg Prolonged-Release Tablets	29831/0636
Oxeltra 80mg Prolonged-Release Tablets	29831/0637

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