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Package leaflet: Information for the user

Oxeltra 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg
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

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 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;
- are under 18 years of age.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if you:
- are or have ever been addicted to opioids, alcohol, prescription medicines or illegal drugs;
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs;
- feel you need to take more 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 disorders;
- 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 a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea;
- have liver or kidney problems.

Taking this medicine regularly, particularly for a long time, can lead to addiction. 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.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

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. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. 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.

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

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

Children and adolescents
Oxeltra should not be used in patients under 18 years of age.

Other medicines and Oxeltra tablets
Concomitant use of opioids and benzodiazepines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor does prescribe benzodiazepines or related drugs with opioids the dosage and duration of concomitant treatment should be limited by your doctor.

The risk of side effects increases, if you use antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine). These medicines may interact with oxycodone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms. Please follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed.

Tell your doctor or pharmacist if you are taking:
- a type of medicine known as monoamine oxidase inhibitor or you have taken this type of medicine in the last two weeks;
- medicines to help you sleep or stay calm (for example hypnotics or sedatives, including benzodiazepines);
- medicines to treat depression (such as paroxetine);
- medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptic drugs);
- other strong analgesics or 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.

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

Pregnancy
Do not take Oxeltra if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber 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 which could affect your ability to drive or use machinery (see section 4 for a full list of side effects). These are usually most noticeable when you first start taking the tablets, 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-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.

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. The label on your medicine will tell you how many tablets to take and how often.

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.

Adults (over 18 years of age)
The usual starting dose is one 10 mg 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.**

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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.

Use in 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 straight away. 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.

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.

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 tablets.

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.

How do I know if I am addicted?
If you notice any of the following signs whilst taking Oxeltra, 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 prescriber.

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):
- a need to take higher doses to gain the same level of pain relief (tolerance)
- 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, low blood pressure, a feeling of 'faintness' especially on standing up, 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 (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
- development of a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea
- long term use of Oxeltra 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.

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 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg or 80 mg 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:
5 mg – polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b), indigo carmine aluminium lake (E132) and iron oxide yellow (E172).
10 mg – hypromellose (E464), titanium dioxide (E171), macrogol (E1521), polysorbate (E433).
15 mg – polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b), iron oxide black (E172) and iron oxide yellow (E172).
20 mg - polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b) and iron oxide red (E172).
30 mg - polyvinyl alcohol (E1203), macrogol (E1521), talc (E553b), iron oxide red (E172), iron oxide black (E172) and indigo carmine aluminium lake (E132).
40 mg - polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b) and iron oxide yellow (E172).
60 mg – polyvinyl alcohol (E1203), macrogol (E1521), talc (E553b), iron oxide red (E172), carmine and iron oxide black (E172).
80 mg – 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:
5 mg - blue, 10 mg - white, 15 mg – grey, 20 mg - pink, 30 mg – brown, 40 mg - yellow, 60 mg – red, 80 mg – 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	PL 29831/0630
Oxeltra 10mg Prolonged-Release Tablets	PL 29831/0631
Oxeltra 15mg Prolonged-Release Tablets	PL 29831/0632
Oxeltra 20mg Prolonged-Release Tablets	PL 29831/0633
Oxeltra 30mg Prolonged-Release Tablets	PL 29831/0634
Oxeltra 40mg Prolonged-Release Tablets	PL 29831/0635
Oxeltra 60mg Prolonged-Release Tablets	PL 29831/0636
Oxeltra 80mg Prolonged-Release Tablets	PL 29831/0637

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