

Abbreviated Prescribing Information: Oxeltra 5 mg, 10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg Prolonged-Release

Tablets (Oxycodone hydrochloride 5mg, 10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg).

Please refer to the Summary of Product Characteristics (SmPC) before prescribing

Presentation: Prolonged-release film-coated tablets in different colours, round biconvex marked OX 5, OX10, OX15, OX20, OX30, OX40, OX60 or OX80 on one side.

Indications: For treatment of moderate to severe pain with cancer and postoperative pain; for severe pain requiring strong opioid. **Dosage and Administration:** Not for use as a prn analgesic. Dosage depends on severity of pain and previous history of analgesic requirements. The correct dosage is that which controls pain and is tolerated for a full 12 hours. Titrate to pain relief with dose increments of 25-50%. Usual starting dose for opioid naïve patients is 10 mg 12 hourly which should be carefully titrated once a day. Patients switching from oral morphine should have their dose adjusted in a ratio of 10mg oral oxycodone for 20 mg oral morphine. No dosage adjustment required in elderly patients. Oxeltra should not be used in patients under 18 years of age. In patients with hepatic or renal impairment the recommended starting dose should be reduced by 50%. Oxeltra should not be used for longer than necessary. On discontinuation taper the dose gradually to prevent withdrawal symptoms. Tablets must be swallowed whole – administration of broken, chewed or crushed tablets leads to rapid release and absorption of a potentially fatal dose. **Contraindications:** Hypersensitivity to oxycodone or any of the excipients in the product, any situation where opioids are contraindicated: severe respiratory depression with hypoxia, elevated serum carbon dioxide levels (hypercarbia), paralytic ileus, acute abdomen, delayed gastric emptying, chronic constipation, severe COPD, cor pulmonale, severe bronchial asthma, moderate to severe hepatic impairment, hereditary galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. **Warnings and Precautions:** Opioid excess can cause respiratory depression. Use with caution in debilitated elderly, patients with severely impaired pulmonary function, impaired hepatic or renal function, following abdominal surgery, in patients with myxoedema, hypothyroidism, Addison's disease, toxic psychosis, prostate hypertrophy, adrenocortical insufficiency, alcoholism, delirium tremens, disease of the biliary tract, IBD, pancreatitis, hypotension, hypovolemia, raised intracranial pressure, intracranial lesions, head injury, reduced level of consciousness of uncertain origin, sleep apnoea or patients taking benzodiazepines, other CNS depressants (including alcohol) or MAO inhibitors. Coadministration with MAOIs or within 2 weeks of their discontinuation should be avoided. Opioids may cause or worsen pre-existing central sleep apnoea (CSA) or sleep related hypoxaemia. Consider reduced total dosage in patients with CSA. Concomitant use of sedatives such as benzodiazepines may result in sedation, respiratory depression, coma and death and should be reserved for those patients for whom alternative treatment is not possible. In this case use the lowest effective dose for the shortest duration possible, and follow closely for signs of respiratory depression. Avoid concomitant use with alcohol. Oxeltra should not be used where there is a possibility of paralytic ileus. Oxeltra is not recommended for preoperative use and within 12-24 hours postoperatively. Oxeltra 60mg and 80mg should not be used in opioid naïve patients; this strength may cause fatal respiratory depression. Prolonged use may lead to drug dependence (addiction), even at therapeutic doses. This risk is increased in those with history of substance misuse disorder (including alcohol misuse) or mental health disorder. Patients may develop tolerance. Patients should be closely monitored for signs of misuse, abuse, or addiction. Drug withdrawal syndrome may occur upon abrupt cessation of therapy or dose reduction. If used during pregnancy, newborn infants may experience neonatal withdrawal syndrome. Hyperalgesia may be diagnosed if the patient on long-term opioid therapy presents with increased pain resulting from development of tolerance. Hyperalgesia may resolve with a reduction of opioid dose. Abuse of oral dosage forms of oxycodone via parenteral administration can result in local tissue necrosis, infection, pulmonary granulomas, increased risk of endocarditis and valvular heart injury which may be fatal. Opioids may influence the hypothalamic-pituitary-adrenal or – gonadal axis increasing serum prolactin or decreasing plasma cortisol and testosterone **Drug interactions:** Concomitant use of sedative agents such as benzodiazepines with opioids can increase risk of sedation, respiratory depression, coma and death. Oxeltra potentiates the effects of alcohol, anxiolytics, anaesthetics, hypnotics, antipsychotics, antidepressants, phenothiazines,, other opioids, gabapentinoids, muscle relaxants and antihypertensives. MAOIs in combination with narcotic analgesics can produce CNS excitation or depression associated with hypertensive or hypotensive crisis. Administration with anticholinergic agents may result in increased anticholinergic adverse effects. Administration with Selective Serotonin Re-uptake Inhibitors (SSRI) or a Serotonin Norepinephrine Re-uptake Inhibitors (SNRI) may cause serotonin toxicity. Oxycodone should be use with caution at a reduced dosage in patients using these medications. Oxycodone is metabolized by CYP3A4 and by CYP2D6. Inhibitors of CYP3A4 such as macrolide antibiotics (clarithromycin, erythromycin, telithromycin) antifungals (ketoconazole, voriconazole, itraconazole, posaconazole) protease inhibitors (boceprevir, ritonavir, indinavir, nelfinavir, saquinavir), cimetidine and grapefruit juice may reduce clearance and increase the plasma concentration of oxycodone. CYP3A4 inducers (e.g. rifampicin, carbamazepine, phenytoin and St John's Wort) may induce the metabolism and increase the clearance of oxycodone, reducing its plasma concentration. CYP2D6 inhibitors (e.g. paroxetine, quinidine) may decrease the clearance of oxycodone leading to increased plasma concentrations of oxycodone. **Pregnancy and lactation:** Not recommended in pregnancy or labour. Regular use during pregnancy may cause drug dependence in the foetus, leading to withdrawal symptoms in the neonate. Use during labour may depress respiration in the neonate and an antidote for the child should be readily available. Not recommended in nursing women as oxycodone may be secreted in breast milk and may cause respiratory depression in the infant. **Undesirable effects:** Very common ($\geq 1/10$): somnolence, dizziness, headache, constipation, nausea, vomiting and pruritus. Common ($\geq 1/100$ to $< 1/10$): decreased appetite, anxiety, confusional state, depression, insomnia, nervousness, abnormal thinking, abnormal dreams, tremor, lethargy, sedation, dyspnoea, bronchospasm, cough decreased, abdominal pain, diarrhoea, dry mouth, dyspepsia, rash, hyperhidrosis and asthenia, fatigue. Uncommon ($\geq 1/1,000$ to $< 1/100$): hypersensitivity, dehydration, agitation, affect lability, euphoric mood, hallucinations, decreased libido, disorientation, mood altered, restlessness, dysphoria, amnesia, convulsion, hypertonia, hypoesthesia, involuntary muscle contractions, speech disorder, syncope, paraesthesia, dysgeusia, hypotonia, visual impairment, miosis, vertigo, palpitations, supraventricular tachycardia, vasodilatation, facial flushing, respiratory depression, hiccups, dysphagia, flatulence, eructation, ileus, gastritis, increased hepatic enzymes, biliary colic, dry skin, exfoliative dermatitis, urinary retention, ureteral spasm, erectile dysfunction, hypogonadism, chills, drug withdrawal syndrome, malaise, oedema, peripheral oedema, drug tolerance thirst and pyrexia. Rare ($\geq 1/10,000$ to $< 1/1,000$): hypotension, orthostatic hypotension and urticaria. Frequency unknown: anaphylactic reaction, anaphylactoid reaction, aggression, drug dependence, hyperalgesia, sleep apnoea syndrome, dental caries, cholestasis, amenorrhoea, and drug withdrawal syndrome neonatal. For further information on adverse effects please refer to the SmPC. **Legal Category:** POM **Marketing Authorization Number and Holder:** Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK. **Marketing Authorization Number:** PL 29831/0631-0637 **Package quantities and basic NHS price:** 28 x 5mg £3.13: 56 x 10mg £6.26: 56 x 15mg £9.53: 56 x 20mg £12.52: 56 x 30mg £19.06: 56 x 40mg £25.05: 56 x 60mg £38.12: 56 x 80mg £50.10 **Date of API Preparation:** 10/08/2022

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Wockhardt UK Ltd by calling: +44 (0) 1978 669272 or email drug.safety@wockhardt.co.uk