



OxyContin advertisement.

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release

Release them from severe pain
so they can return to their lives



Prolonged release oxycodone hydrochloride tablets

OxyContin® 5 mg, 10 mg, 20 mg, 40 mg, 80 mg tablets ▽

Prescribing Information United Kingdom

Presentation Film-coated, prolonged release tablets containing oxycodone hydrochloride, marked OC on one side and the strength on the other. Colours: 5 mg - blue, 10 mg - white, 20 mg - pink, 40 mg - yellow, 80 mg - green. **Indications** For the treatment of moderate to severe pain in patients with cancer and post-operative pain, and severe pain requiring the use of a strong opioid. **Dosage and administration** *OxyContin* tablets must be swallowed whole, and not chewed. **Elderly and adults over 18 years:** *OxyContin* tablets should be taken at 12-hourly intervals. The dosage is dependent on the severity of the pain and the patient's previous history of analgesic requirements. The usual starting dose for opioid naïve patients or patients presenting with severe pain uncontrolled by weaker opioids is 10 mg, 12-hourly. Some patients may benefit from a starting dose of 5 mg to minimise the incidence of side effects. Opioid naïve patients with mild to moderate renal and/or mild hepatic impairment may be started on 5 mg 12-hourly and titrated to pain relief. Any dose increases should be made, where possible, in 25% - 50% increments. Patients transferring from morphine should have the daily dose based on the following ratio: 10 mg oral oxycodone is equivalent to 20 mg oral morphine. Opioids are not first-line therapy in non-malignant pain, nor are they recommended as the only treatment. The need for continued treatment in non-malignant pain should be assessed at regular intervals. **Children under 18 years:** Not recommended. **Contra-indications** Respiratory depression, head injury, paralytic ileus, acute abdomen, delayed gastric emptying, chronic obstructive airways disease, cor pulmonale, chronic bronchial asthma, hypercarbia, known oxycodone sensitivity, moderate

to severe hepatic impairment, severe renal impairment, chronic constipation, concurrent administration of monoamine oxidase inhibitors or within 2 weeks of discontinuation of their use, galactose intolerance, lactase deficiency, glucose galactose malabsorption. Not recommended for pre-operative use or for the first 24 hours post-operatively. **Pregnancy.** **Precautions and warnings.** Hypothyroidism, opioid dependent patients, raised intracranial pressure, hypotension, hypovolaemia, toxic psychosis, diseases of the biliary tract, pancreatitis, inflammatory bowel disorders, prostatic hypertrophy, adrenocortical insufficiency, acute alcoholism, delirium tremens, chronic renal and hepatic disease, severe pulmonary disease, debilitated patients, history of alcohol and/or drug abuse. Do not use where there is a possibility of paralytic ileus occurring and if this is suspected or occurs during use discontinue immediately. Patients who are to undergo cordotomy or other pain relieving surgical procedures should not receive *OxyContin* tablets for 24 hours before surgery. *OxyContin* 80 mg should not be used in opioid naïve patients. *OxyContin* tablets should be used with caution following abdominal surgery, and should not be used until normal bowel function returns. *OxyContin* tablets have an abuse liability similar to other strong opioids. *OxyContin* tablets must be swallowed whole and not broken, chewed or crushed which leads to a rapid release and absorption of a potentially fatal dose of oxycodone. **Interactions** As with other opioids, *OxyContin* tablets interact with tranquillisers, anaesthetics, hypnotics, anti-depressants, sedatives, alcohol, other opioids and antihypertensives. **Pregnancy and lactation** Not recommended. **Side-effects** Common adverse drug reactions are constipation, nausea, vomiting, dry mouth, anorexia, dyspepsia, abdominal pain, diarrhoea, headache, confusion, asthenia, faintness, dizziness,

sedation, anxiety, abnormal dreams, nervousness, insomnia, thought abnormalities, drowsiness, twitching, orthostatic hypotension, bronchospasm, dyspnoea, decreased cough reflex, rash, pruritus, sweating, chills. Some side-effects which are uncommon but could be serious are biliary spasm, ileus, gastritis, hallucinations, hypertension, depression, withdrawal syndrome, paraesthesia, seizure, urinary retention, uretic spasm, decreased libido, palpitations, supraventricular tachycardia, hypotension, syncope, oedema, overdose may produce respiratory depression, exfoliative dermatitis, allergic reaction and anaphylaxis. Please refer to the SPC for further details of other uncommon side-effects. Tolerance and dependence may occur. It may be advisable to taper the dose when stopping treatment to prevent withdrawal symptoms. Addiction in properly managed patients is reported to be rare. **Legal category** CD (Sch2) **POM Package quantities and price** 5 mg - £11.58 (28 tablets), 10 mg - £23.14 (56 tablets), 20 mg - £46.29 (56 tablets), 40 mg - £92.59 (56 tablets), 80 mg - £185.18 (56 tablets) **Marketing Authorisation numbers** PL 16950/0097-0100, 0123 **Marketing Authorisation holder** Napp Pharmaceuticals Limited, Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK. Tel: 01223 424444 Member of the Napp Pharmaceutical Group. Further information is available from Napp Pharmaceuticals Limited.

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European Patent (UK) 0 253 104

European Patent (UK) 0 576 643

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