Abtard® prolonged-release tablets (oxycodone hydrochloride) - abbreviated prescribing information

Refer to the Summary of Product Characteristics for full product information.

Presentation: Prolonged-release tablets containing 5, 10, 15, 20, 30, 40, 60 or 80 mg of oxycodone hydrochloride, equivalent to 4.5, 9.0, 13.5, 18, 27, 36, 54 or 72 mg of oxycodone.

Indication: Abtard is indicated in adults and adolescents from 12 years of age for:
• Treatment of severe pain, which can be adequately managed only with opioid analgesics

Dosage and Administration: Refer to SmPC for details and recommendations
Adults and adolescents (12 years and older): Abtard may be taken with or without food with sufficient liquid. It must be swallowed whole and not broken, chewed or crushed. Abtard should be taken in the determined dosage twice daily in a fixed time schedule.
The usual starting dose for an opioid naïve patient is 10 mg oxycodone hydrochloride at 12 hour intervals. Some patients may benefit from a starting dose of 5 mg to minimize the incidence of adverse reactions. Patients already receiving opioids may be initiated on higher Abtard doses depending on their previous opioid experience. 10 to 13 mg oxycodone hydrochloride correspond to approximately 20 mg of morphine sulphate, both in the prolonged-release formulation.
Due to individual differences in sensitivity for different opioids, it is recommended that patients should start conservatively with Abtard after conversion from other opioids, with 50-75% of the calculated oxycodone dose.
Dose adjustment: Some patients given around-the-clock controlled release opioid therapy will require immediate release analgesic as "rescue" from breakthrough pain. The single rescue medication should amount to a sixth of the equianalgesic daily dose. The need for more than two "rescues" per day is usually an indication that the controlled release Abtard basal dose requires upward titration. Titration should be done at a frequency of no less than 1 or 2 days until a stable 12-hour1y dose is reached. Beyond the increase from 10 mg to 20 mg every 12 hours, increase the dose by approximately one-third until the desired effect is obtained.
Older people: A dose adjustment is usually not necessary in elderly patients without clinically manifest impairment of hepatic or renal function.
Patients at risk: e.g. with renal or hepatic insufficiency, low body weight or slow metabolisers, who are opioid naïve, should initially be treated with half the dose usually recommended for adults. Therefore the lowest recommended dosage 10 mg oxycodone hydrochloride may not be suitable as a starting dose and in such cases 5 mg oxycodone hydrochloride can be used.
Children and adolescents: Abtard is not recommended for use in children below the age of 12 years due to insufficient data on safety and efficacy.

Contra-indications: Hypersensitivity to the active substance or to any of the excipients of the tablets. Abtard must not be used in any situation where opioids are contraindicated, for example: severe respiratory depression with hypoxia and/or hypercapnia; severe chronic obstructive pulmonary disease; cor pulmonale; severe bronchial asthma; elevated carbon dioxide levels in the blood; paralytic ileus; acute abdomen, delayed gastric emptying.

Precautions and Warnings: Abtard is not recommended for use in children below the age of 12 years due to insufficient data on safety and efficacy. Caution must be exercised when administering oxycodone to the elderly or debilitated patients, patients with severe impairment of pulmonary, hepatic or renal function, patients with myxoedema, hypothyroidism, adrenal insufficiency (Addison's disease), intoxication psychosis (e.g. alcohol), prostatic hypertrophy, adrenocortical insufficiency, alcoholism, known opioid dependence, delirium tremens, pancreatitis, diseases of the biliary tract, inflammatory bowel disorders, biliary or ureteric colic, hypotension, hypovolaemia, conditions with increased brain pressure such as head injury, disturbances of circulatory regulation, epilepsy or seizure tendency or patients taking MAO inhibitors. With the occurrence or suspicion of paralytic ileus, oxycodone should be immediately discontinued. Respiratory depression is the most significant risk induced by opioids and is most likely to occur in elderly or debilitated patients. The respiratory depressant effects of oxycodone may cause increased carbon dioxide levels in the blood and hence in the cerebrospinal fluid. Opioids may cause severe decrease in blood pressure in predisposed patients.
As with all opioid preparations, oxycodone products should be used with caution following abdominal surgery as opioids are known to impair intestinal motility and should not be used until the physician is assured of normal bowel function.
The patient may develop tolerance to the drug with chronic use and require progressively higher doses to maintain pain control. Prolonged use of this product may lead to physical dependence and a withdrawal syndrome may occur upon abrupt cessation of therapy. When a patient no longer requires therapy with oxycodone, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal. Withdrawal symptoms may include yawning, mydriasis, lacrimation, rhinorrhoea, tremor, hyperhidrosis, anxiety, agitation, convulsions and insomnia.
Hyperalgesia that will not respond to a further dose increase of oxycodone may very rarely occur, particularly in high doses. An oxycodone dose reduction or change to an alternative opioid may be required.
Oxycodone has an abuse profile similar to other strong agonist opioids. Oxycodone may be sought and abused by people with latent or manifest addiction disorders. However, when used as instructed in patients suffering from chronic pain, the risk of physical or psychological dependence is markedly reduced. There is potential for development of psychological dependence [addiction] to opioid analgesics, including oxycodone, however, data are not available to establish the true incidence of addiction in chronic pain patients.
Abtard should be used with particular care in patients with a history of alcohol and drug abuse. Concomitant use of alcohol and Abtard may increase the undesirable effects of Abtard; concomitant use should be avoided.
The use of Abtard may produce positive results in doping controls. Use of Abtard as a doping agent may become a health hazard.
Abtard is not recommended for pre-operative use or within the first 12-24 hours post-operatively. Depending on the type and extent of surgery, the anaesthetic procedure selected, other co-medication and the individual condition of the patient, the exact timing for initiating post-operative treatment with Abtard depends on a careful risk-benefit assessment for each individual patient.
Fertility, pregnancy and lactation: Use of this medicinal product should be avoided to the extent possible in patients who are pregnant or lactating.
Effects on ability to drive and use machines: Abtard may impair the ability to drive and use machinery. However, with stable therapy, a general ban on driving a vehicle is not necessary. Therefore, the physician must assess the individual situation.

Interactions: There can be an enhanced CNS depressant effect during concomitant therapy with drugs which affect the CNS such as other opioids, sedatives, hypnotics, antidepressants, antipsychotics, anaesthetics, muscle relaxants, antihistamines and antiemetics.
Monoamine oxidase inhibitors causes CNS excitation or depression associated with hyper- or hypotensive crisis. Oxycodone should be used with caution in patients administered MAO-inhibitors or who have received MAO-inhibitors during the last two weeks.
Alcohol may enhance the pharmacodynamic effects of Abtard; concomitant use should be avoided.
Agents with anticholinergic effects (e.g. psychotropic drugs, antihistamines, antiemetics, medicinal products against Parkinson's disease) may intensify the anticholinergic adverse drug reactions of oxycodone like constipation, dry mouth or micturition disorders.
Cimetidine can inhibit the metabolism of oxycodone.
Oxycodone is metabolised mainly by CYP3A4, with a contribution from CYP2D6. The activities of these metabolic pathways may be inhibited or induced by various co-administered drugs or dietary elements.
CYP3A4 inhibitors, such as macrolide antibiotics (e.g. clarithromycin, erythromycin and telithromycin), azol-antifungals (e.g. ketoconazole, voriconazole, itraconazole, and posaconazole), protease inhibitors (e.g. boceprevir, ritonavir, indinavir, nelfinavir and saquinavir), cimetidine and grapefruit juice may cause a reduced clearance of oxycodone that could cause an increase of the plasma concentrations of oxycodone. CYP3A4 inducers, such as rifampicin, carbamazepine, phenytoin and St John's Wort may induce the metabolism of oxycodone, increasing the clearance of oxycodone that could cause a reduction of the plasma concentrations of oxycodone. Therefore the oxycodone dose may need to be adjusted accordingly with concomitant use of CYP3A4 inhibitors or enhancers.

Side-effects: Refer to SmPC for full list. Oxycodone may cause respiratory depression, miosis, bronchial spasms and spasms of the smooth muscle and may suppress the cough reflex.
The most commonly reported Adverse Drug Reactions (ADRs) are: Decreased appetite, anxiety, confusional state, depression, insomnia, nervousness, abnormal thinking, amnesia, isolated cases of speech disorders, somnolence, dizziness, headache, asthenia, tremor, dyspnoea, bronchospasm, constipation, vomiting, nausea, dry mouth rarely accompanied by thirst, gastointestinal disorders such as abdominal pain, diarrhoea, dyspepsia, loss of appetite, pruritus, skin eruptions including: rash; in rare cases increased photosensitivity; in isolated cases urticaria or exfoliative dermatitis; hyperhidrosis, micturition disturbances (increased urge to urinate), sweating, asthenic conditions.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard Adverse events should also be reported to Medical Services Information - enquiries@medinformation.co.uk

Price: 5 mg x 28 £6.26, 10 mg x 56 £12.52, 15 mg x 56 £19.06, 20 mg x 56 £25.04, 30 mg x 56 £38.11, 40 mg x 56 £50.09, 60 mg x 56 £76.24, 80 mg x 56 £100.19

Legal category: CD (Sch2) POM.

Further Information: For full prescribing information see Summary of Product Characteristics.

MA Holder: DB Ashbourne Ltd, The Rectory, Braybrooke Road, Arthingworth, Market Harborough, Leicestershire, LE16 8JT.
Telephone: 01858 525643. Fax: 01858 525383.

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DB ASHBOURNE Ltd

www.dbashbourne.com