OxyContin advertisement.

[s.l.]: [s.n.], 1997

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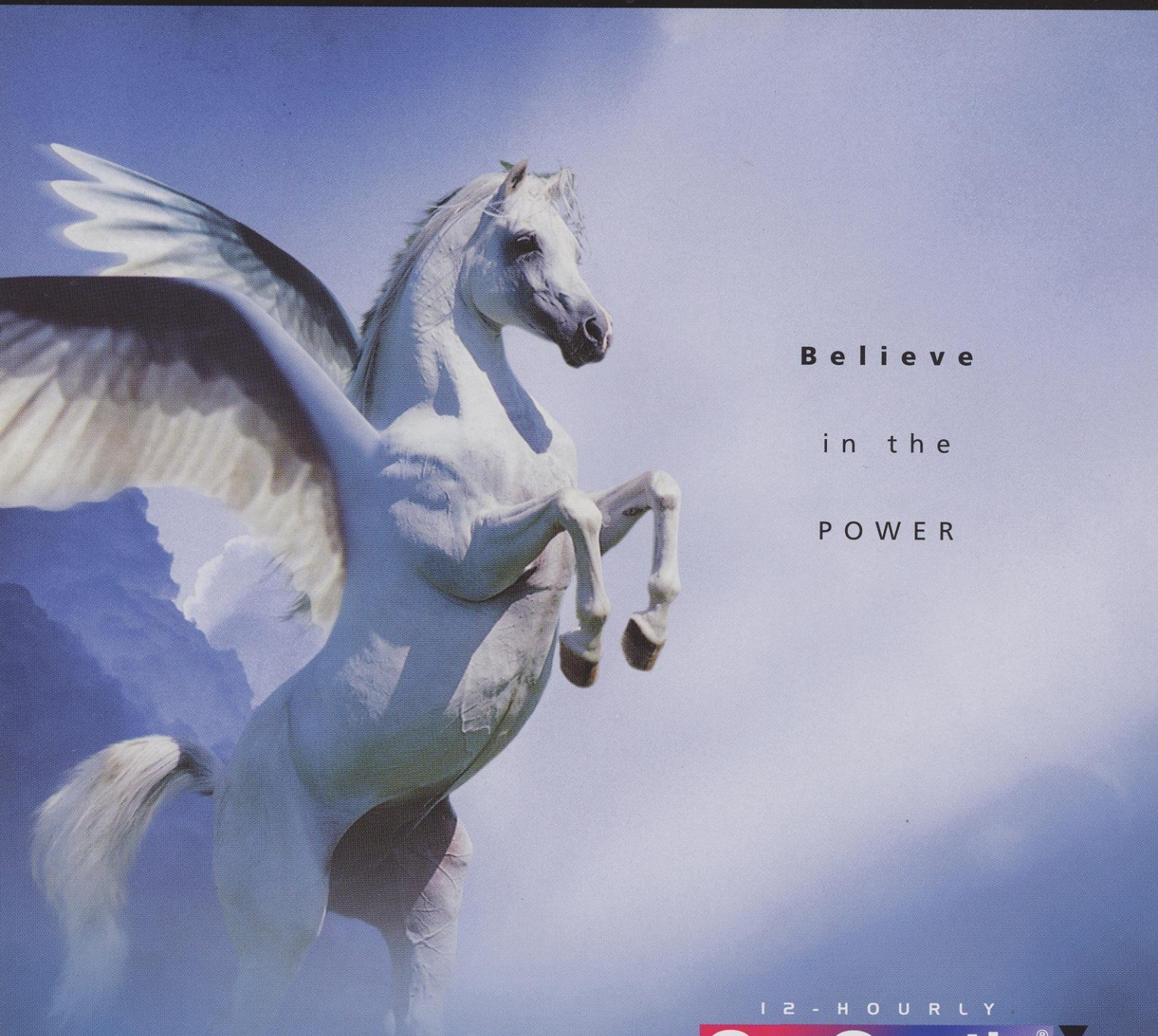

NEW FOR MODERATE TO SEVERE PAIN
in malignancy and post-operative patients

12-HOURLY
OxyContin®▼
Modified release oxycodone hydrochloride tablets

start with it, **stay** with it, **trust** i

OxyContin® 10 mg, 20 mg, 40 mg, 80 mg▼ tablets PRESCRIBING INFORMATION UK Presentation Film-coated, modified release tablets containing oxycodone hydrochloride, marked OC on one side and the strength of oxycodone hydrochloride on the other. The 10 mg tablets are white and contain 10 mg of oxycodone hydrochloride (9 mg of oxycodone). The 20 mg tablets are pink, and contain 20 mg of oxycodone hydrochloride (18 mg of oxycodone). The 40 mg tablets are yellow, and contain 40 mg of oxycodone hydrochloride (36 mg of oxycodone). The 80 mg tablets are green, and contain 80 mg of oxycodone hydrochloride (72 mg of oxycodone). **Indications** For the treatment of moderate to severe pain in patients with cancer and post-operative pain. **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. If higher doses are necessary, 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. For most patients the maximum dose of OxyContin is 200 mg, 12-hourly. However, a few patients may require higher doses. Doses in excess of 1000 mg have been reported. *Children under 18 years:* Not recommended. **Contra-indications** Respiratory depression, head injury, paralytic ileus, acute abdomen, delayed gastric emptying, chronic obstructive airways disease, 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. Not recommended for pre-operative use or for the first 24 hours post-operatively. Pregnancy. **Precautions and warnings** A reduction in dosage may be advisable in hypothyroidism. Use with caution in opioid dependent patients and in patients with raised intracranial pressure, hypotension, hypovolaemia, diseases of the biliary tract, pancreatitis, inflammatory bowel disorders, prostatic hypertrophy, adrenocortical insufficiency, acute alcoholism, chronic renal and hepatic disease, and debilitated patients. OxyContin should not be used where there is a possibility of paralytic ileus occurring. Should paralytic ileus be suspected or occur during use, OxyContin should be discontinued immediately. Patients who are to undergo cordotomy or other pain relieving surgical procedures should not receive OxyContin for 24 hours before surgery. If further treatment with OxyContin is then indicated the dosage should be adjusted to the new post-operative requirement. OxyContin 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. **Pregnancy and lactation** Not recommended. Oxycodone is secreted in breast milk and may cause respiratory depression in the newborn. OxyContin should, therefore, not be used in breast-feeding mothers. **Side-effects** Adverse drug reactions are typical of full opioid agonists. Tolerance and dependence may occur. The most common adverse drug reactions seen during therapy are constipation (which may be prevented with an appropriate laxative), nausea, dizziness, pruritus, urticaria, vomiting, headache, dry mouth, sweating, drowsiness and asthenia. If nausea and vomiting are tro blesome, oxycodone may be combined with an antiemetic. Occasional adverse reactio are anorexia, nervousness, insomnia, fever, confusion, diarrhoea, abdominal pain, vaso lation, dyspepsia, paraesthesia, rash, anxiety, euphoria, depression, dyspnoea, postu hypotension, chills, abnormal dreams, thought abnormalities, hiccups. Vertigo, twitchir gastritis, disorientation, facial flushing, mood changes, palpitations, hallucinations, brc chospasm and colic may occur in a few patients. Micturition may be difficult and there m be biliary or ureteric spasm. Overdose may produce respiratory depression. Rarely, cli cally relevant reductions in blood pressure and heart rate have been observed. **Legal ca egory** CD (Sch2) POM. **Package quantities and price** Blister packs of 56 tablets. 10 mg £21.43. 20 mg – £42.86. 40 mg – £85.73. 80 mg – £171.46. **Marketing Authorisation numbe** PL 16950/0097-0100. **Marketing Authorisation holder** Napp Pharmaceuticals Limite Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK. Tel: 01223 424444. Memb of the Napp Pharmaceutical Group. Further information is available from Na Pharmaceuticals Limited. Date of preparation November 1999. ® OxyContin and the NA device are Registered Trade Marks. © Napp Pharmaceuticals Limited 2000. Europe Patent (UK) 0 253 104. European Patent (UK) 0 576 643. European Patent Application N 96102992.3. Horse was supplied by Larrigan Equestrian Promotions.

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