New Drugs

FDA Approval for Oxymorphone HCl:
Extended Release and Immediate Release Tablets

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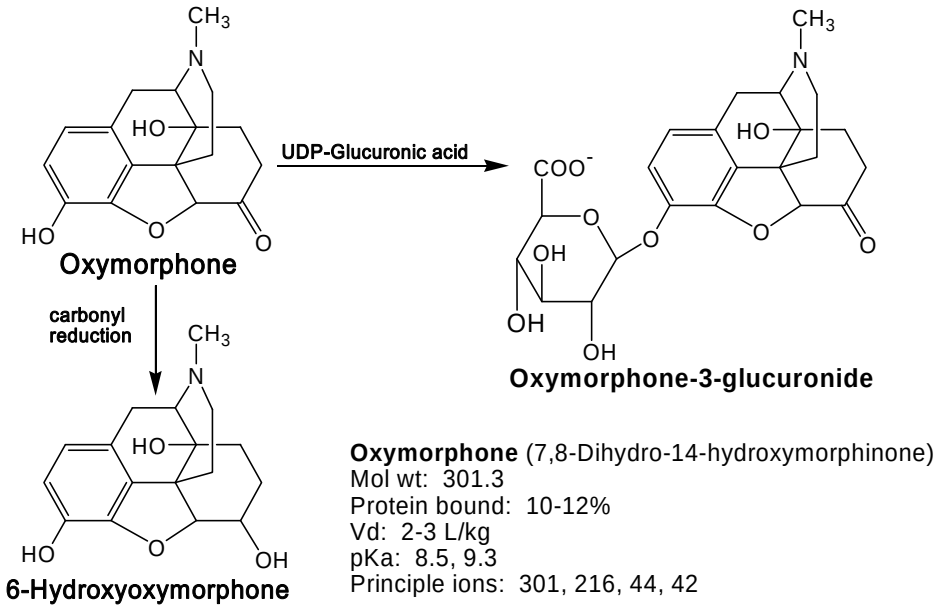
Under the trade name, Numorphan®, oxymorphone has only been available in the US in suppository and injectable formulations. Typically, when oxymorphone is encountered in forensic samples, it is as the *O*-desmethyl metabolite of oxycodone. However, on June 23, 2006 the FDA gave final approval for two new oral formulations of oxymorphone for the treatment of moderate to severe pain. Trade names for the immediate and extended release tablets are Opana® and Opana® ER, respectively. The extended release tablets will be marketed in 5, 10, 20 and 40 mg strengths, whereas the immediate release tablets will be available in 5 and 10 mg. Endo Pharmaceuticals expects combined sales for these medications of $20 to $30 million in 2006. As with Oxycontin®, product warnings for the extended release product caution against crushing the tablets.

The potency of oxymorphone may be somewhat greater than oxycodone and similar to that of hydromorphone (1). Metabolism of oxymorphone occurs via reduction to 6-hydroxyoxymorphone and conjugation forming primarily oxymorphone 3-glucuronide (2).



Oxymorphone (7,8-Dihydro-14-hydroxymorphinone)
Mol wt: 301.3
Protein bound: 10-12%
Vd: 2-3 L/kg
pKa: 8.5, 9.3
Principle ions: 301, 216, 44, 42

References:

1. B.G. Katzung. *Basic & Clinical Pharmacology*, 9th ed., McGraw-Hill, New York, NY, pp 497-516 (2004).

2. Adams MP, Ahdieh H. Single- and multiple-dose pharmacokinetic and dose-proportionality study of oxymorphone immediate-release tablets. Drugs in R&D. 6:91-9 (2005).

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