

## New Oxycodone Formulation: *OxyNeo*

### **Background**

Health Canada has approved a new formulation of *OxyContin* called *OxyNeo*. This formulation has been available in the U.S. since the spring of 2010.<sup>1</sup> Questions will arise about the new formulation as the old formulation disappears from pharmacy shelves in Canada in early 2012. This article explains the rationale for the new formulation, compares it to the old formulation, and discusses patient care implications.

### **Rationale for the New Formulation**

*OxyContin* is indicated for the treatment of moderate-to-severe pain when around-the-clock analgesia is needed for at least several days. It is dosed every 12 hours.<sup>2</sup>

According to the U.S. Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health, approximately half a million people used *OxyContin* non-medically for the first time in 2008.<sup>3</sup> The main reason *OxyContin* is abused is because, like other opioids, it can cause euphoria.<sup>4</sup> But the U.S. Drug Enforcement Administration (DEA) feels that aggressive *OxyContin* marketing in the U.S. exacerbated the abuse and diversion potential of *OxyContin*. Aggressive marketing led to increased prescribing, sometimes by prescribers not familiar with pain management.<sup>5</sup> The resulting widespread availability of *OxyContin* increased opportunities for abuse and diversion.<sup>4</sup> The manufacturer, Purdue Pharma, also feels that media coverage contributed to the problem.<sup>5</sup>

Because of *OxyContin*'s controlled-release mechanism and extended dosing interval, each tablet contains a large quantity of oxycodone. Patients intent upon abusing *OxyContin* have cut, broken, chewed, crushed, or dissolved the tablets to release the medication all at once.<sup>3</sup> The crushed tablets can be snorted, or dissolved and injected, to get a higher dose with a faster onset compared to swallowing the tablet whole.<sup>4</sup> *OxyNeo* is designed to discourage misuse of the

medication by making the tablets more tamper-resistant.<sup>3</sup>

### **What's New**

The reformulated tablets contain polyethylene oxide.<sup>6</sup> Polyethylene oxide is also found in *Concerta* (methylphenidate extended-release tablets) as part of the controlled-release mechanism and serves as an abuse deterrent.<sup>7</sup> Polyethylene oxide is a nonionic hydrophilic polymer that is insoluble in alcohols. Upon contact with water it forms a viscous gel.<sup>6</sup> Attempts to dissolve the tablets in liquid result in a gummy substance that cannot be injected or snorted.<sup>4,6,8</sup> *OxyNeo* is harder to cut, chew, break, or crush.<sup>4,8</sup> The tablets either do not break, or break into pieces that retain some controlled-release functionality. However, crushing followed by dissolution can release over 75% of the dose, depending on the solvent.<sup>8</sup> Of course, the new formulation can still be abused simply by taking the tablet orally.<sup>3</sup> This was, in fact, the most common route of *OxyContin* abuse in the U.S.<sup>8</sup>

*OxyNeo* tablets have the imprint "ON," while the Canadian *OxyContin* formulation has the imprint "CDN." There are no 5, 120, or 160 mg strengths of *OxyNeo*.<sup>2,9</sup> Another difference is that the 10, 15, 20, 30, and 40 mg *OxyNeo* tablets are slightly thicker than, and the 60 mg and 80 mg tablets are slightly larger than, *OxyContin* tablets.<sup>10</sup>

Because *OxyNeo* forms a gummy gel when wet, patients with narrowing of the esophagus or trouble swallowing should not take *OxyNeo*. To reduce choking risk, patients should take only one *OxyNeo* tablet at a time. They should also avoid wetting or licking the tablet before putting it in their mouth.<sup>9</sup>

### **Therapeutic Efficacy**

The new formulation is bioequivalent to the old formulation.<sup>9</sup> The peak concentration is

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slightly higher, and the time to peak is slightly delayed, for the new formulation. However, this is expected to have minimal clinical significance.<sup>11</sup>

### Commentary

*OxyContin* abuse has been particularly problematic in Atlantic Canada. One percent of students in Ontario report abusing *OxyContin*.<sup>12</sup> In addition, in 2010, *OxyContin* overtook crack cocaine as the most commonly abused drug among clients of an Ottawa rehab centre.<sup>13</sup>

*OxyNeo* is harder to alter for abuse than *OxyContin*, but there is no proof that *OxyNeo* is less subject to abuse or diversion.<sup>19</sup> People can still abuse it by taking large amounts orally. However, since the *OxyContin* reformulation in the U.S., demand on the street appears to have decreased. This seems to have been accompanied by increased demand for oxycodone 30 mg immediate-release tablets, and perhaps heroin.<sup>14</sup>

Expect patients intent upon misusing sustained-release oxycodone to try to obtain the original formulation from illicit sources. In the U.S., some patients claim the new *OxyContin* tablets don't work as well as the old formulation, or cause side effects. They're asking for the "OC" tablets instead of the "OP" tablets (referring to the markings on the reformulated tablets), or the generic. So far, there's no clinical proof of difference in therapeutic efficacy, but efficacy of the new and old formulations have not been compared in pain patients. If patients complain of reduced efficacy or increased side effects, report it to Health Canada or the manufacturer. Try adjusting the dose, or try a different long-acting opioid. For help switching, see our *PL Chart*, "*Equianalgesic Dosing of Opioids for Pain Management*."

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### References

1. Canadian Agency for Drugs and Technologies in Health. Rapid response report: summary with critical appraisal. The safe use of *OxyNEO* and *OxyContin* in adults: a review of the evidence on safety. September 20, 2011. [http://www.cadth.ca/media/pdf/htis/sept-2011/RC0301\\_OxyNEO\\_final.pdf](http://www.cadth.ca/media/pdf/htis/sept-2011/RC0301_OxyNEO_final.pdf). (Accessed December 12, 2011).
2. Product monograph for *OxyContin*. Purdue Pharma. Pickering, ON L1W 3W8. January 2011.
3. FDA news release. FDA approves new formulation for *OxyContin*. April 5, 2010. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm207480.htm>. (Accessed December 12, 2011).
4. FDA. *OxyContin*-questions and answers. April 5, 2010. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm>. (Accessed December 12, 2011).
5. United States General Accounting Office. Report to congressional requestors. Prescription drugs. *OxyContin* abuse and diversion and efforts to address the problem. December 2003. <http://www.gao.gov/new.items/d04110.pdf>. (Accessed December 12, 2011).
6. Center for Drug Evaluation and Research. Application number: 22-272. Chemistry review(s). February 18, 2010. [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2010/022272s000ChemR.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000ChemR.pdf). (Accessed December 12, 2011).
7. FDA. Division of Dockets Management. Docket No. 2004P-0139: supplement to citizen petition. September 17, 2004. <http://www.fda.gov/ohrms/dockets/dailys/04/sep04/092004/04p-0139-sup0002-01-vol6.pdf>. (Accessed December 12, 2011).
8. FDA. A new formulation of *OxyContin* (oxycodone HCl controlled-release) tablets. Presentation to Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee. May 5, 2008. <http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s1-05-Purdue.pdf>. (Accessed December 12, 2011).
9. Product monograph for *OxyNeo*. Purdue Pharma. Pickering, ON L1W 3W8. August 2011.
10. Personal communication (written). Randy Steffan. VP Corporate Affairs. Purdue Pharma. Pickering, ON L1W 3W8. December 16, 2011.

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11. Center for Drug Evaluation and Research. Application number 22-272. Clinical pharmacology and biopharmaceutics review(s). Submission date 4-16-10.  
[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2010/022272s000ClinPharmR.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000ClinPharmR.pdf). (Accessed December 12, 2011).
12. Canadian Centre on Substance Abuse. Fact sheet. *OxyContin*. January 2006.  
<http://www.ccsa.ca/2006%20CCSA%20Documents/ccsa-003642-2006.pdf>. (Accessed December 12, 2011).
13. Anon. *OxyContin* more abused than crack: rehab centre. *CBC News*. March 3, 2010.  
<http://www.cbc.ca/news/canada/ottawa/story/2010/03/03/ott-oxycontin.html>. (Accessed December 12, 2011).
14. Burke J. The *OxyContin* reformulation: is it working? *Pharmacy Times*. May 16, 2011.  
<http://www.pharmacytimes.com/publications/issue/2011/May2011/DrugDiversion-0511>. (Accessed December 12, 2011).

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