

## FDA NEWS RELEASE

For Immediate Release: Apr. 5, 2010

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FDA Approves New Formulation for OxyContin

The U.S. Food and Drug Administration today approved a new formulation of the controlled-release drug OxyContin that has been designed to help discourage misuse and abuse of the medication.

OxyContin is made to slowly release the potent opioid oxycodone to treat patients who require a continuous, around-the-clock opioid analgesic for management of their moderate to severe pain for an extended period of time. Because of its controlled-release properties, each OxyContin tablet contains a large quantity of oxycodone, which allows patients to take their drug less often. However, people intent on abusing the previous formulation have been able to release high levels of oxycodone all at once, which can result in a fatal overdose and contributes to high rates of OxyContin abuse.

The reformulated OxyContin is intended to prevent the opioid medication from being cut, broken, chewed, crushed or dissolved to release more medication. The new formulation may be an improvement that may result in less risk of overdose due to tampering, and will likely result in less abuse by snorting or injection; but it still can be abused or misused by simply ingesting larger doses than are recommended.

“Although this new formulation of OxyContin may provide only an incremental advantage over the current version of the drug, it is still a step in the right direction,” said Bob Rappaport, M.D., director of the Division of Anesthesia and Analgesia Products in the FDA’s Center for Drug Evaluation and Research.

“As with all opioids, safety is an important consideration,” he said. “Prescribers and patients need to know that its tamper-resistant properties are limited and need to carefully weigh the benefits and risks of using this medication to treat pain.”

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.

The manufacturer of OxyContin, Purdue Pharma L.P., will be required to

conduct a postmarket study to collect data on the extent to which the new formulation reduces abuse and misuse of this opioid. The FDA is also requiring a REMS (Risk Evaluation and Mitigation Strategy) that will include the issuance of a Medication Guide to patients and a requirement for prescriber education regarding the appropriate use of opioid analgesics in the treatment of pain.

Purdue Pharma is based in Stamford, Conn.

For more information:

\* OxyContin - Questions and Answers

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.html>

\* A Guide to Safe Use of Pain Medicine

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095673.htm>

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OxyContin - Questions and Answers

(4/5/2010)

The U.S. Food and Drug Administration has approved a new formulation of the controlled-release drug OxyContin. This new formulation is designed to decrease the likelihood that this medication will be misused or abused, and result in overdose. The new formulation adds in new tamper-resistant features aimed at preserving the controlled release of the active ingredient, oxycodone.

The following question and answers provide some additional background information on OxyContin, the misuse and abuse of this drug, and the significance of this new technology.

What is OxyContin?

OxyContin is a prescription narcotic pain reliever that was approved by FDA in 1995. It is manufactured by Purdue Pharma LP, and its active ingredient is oxycodone, a derivative of opium.

How is OxyContin used to treat pain?

OxyContin is made to slowly release the potent opioid oxycodone to treat patients who require around-the-clock medical management with an opioid analgesic for their moderate to severe pain. Because of its

controlled-release properties, each OxyContin tablet contains a large quantity of oxycodone, which allows patients to take their drug less often—a distinct benefit for patients who are in chronic pain.

Why is OxyContin abused?

The primary reason OxyContin is abused is that this drug, like all opioid narcotics, can produce euphoria (a sense of well-being). Euphoria is the primary reason why people use opioids non-medicinally. Chronic non-medicinal use of euphoric-producing drugs can lead to addiction and dependence.

The wide availability of OxyContin, is secondary reason why this drug is popular to use non-medicinally. Although an individual would need a prescription to legally purchase and use OxyContin medicinally, this drug can be easily obtained through illicit channels. The high volume of OxyContin supply available to the public, and the discrepancy between the fair and black market value of the medicine, contributes to diversion, illicit sale, and abuse of OxyContin.

The rates of OxyContin misuse and abuse remain high—in 2008, the number of new nonmedical users of OxyContin aged 12 or older was approximately half a million.<sup>1</sup>

What does the new formulation of OxyContin accomplish? Does it decrease the likelihood that this drug will be misused and abused?

Over time, individuals have learned effective ways to tamper with OxyContin's controlled-release technology. Tampering with the tablet, via cutting, chewing, breaking, or dissolving, can be very dangerous because it releases high levels of oxycodone all at once.

There have been reports of inadvertent overdose with OxyContin after health care practitioners crushed the drug in order to administer it to patients who could not swallow the tablet.

Tampering with tablets is also popular among individuals seeking OxyContin's euphoric properties. By crushing and snorting, or dissolving and injecting, individuals received a much higher and immediate dose of oxycodone than they would if they swallowed the tablet whole.

The reformulated version of OxyContin is intended to prevent immediate access to the full dose of oxycodone via cutting, chewing, or breaking the tablet. Attempts to dissolve the tablets in liquid result in a gummy substance that cannot be drawn up into a syringe or injected.

The new formulation of OxyContin reduces the likelihood that this drug will be misused and abused, although it can not completely eliminate this possibility.

The new formulation can still be abused or misused and result in overdose simply by ingesting or administering it in higher than recommended doses. Health care professionals need to remind their patients of the risks associated with using OxyContin not-as-directed.

How will FDA know if the new version of OxyContin is more resistant to drug misuse and abuse?

FDA is requiring Purdue Pharma LP to conduct a post-marketing study to determine the impact of the new formulation on the use and misuse of OxyContin. Additionally, FDA is requiring the manufacturers to follow a Risk Evaluation and Mitigation Strategy (REMS) for this product, which will include the issuance of a Medication Guide to all patients who will use this product and a requirement for prescriber education on the appropriate use of opioid analgesics in the treatment of pain.

#### References

1. Substance Abuse and Mental Health Services Administration. (2009). Results from the 2008 National Survey on Drug Use and Health: National Findings (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434) Rockville, MD.

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