

Thank you for your recent inquiry regarding oxycodone and acetaminophen tablets USP (CII). You specifically asked about crushing this product. The following information is not intended as medical advice or guidelines, but rather to serve as information for you to utilize with your own clinical judgment.

Oxycodone and acetaminophen tablets USP are indicated for the relief of moderate to moderately severe pain.<sup>1</sup>

Oxycodone and acetaminophen tablets should not be administered to patients with known hypersensitivity to oxycodone, acetaminophen, or any other component of this product. Oxycodone is contraindicated in any situation where opioids are contraindicated, including patients with significant respiratory depression (in unmonitored settings or in the absence of resuscitative equipment) and patients with acute or severe bronchial asthma or hypercarbia. Oxycodone is contraindicated in the setting of suspected or known paralytic ileus.<sup>1</sup>

### **Hepatotoxicity**

Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product.

Mallinckrodt has not performed any studies on the safety and efficacy of using a crushed form of oxycodone and acetaminophen tablets. Because this product is not an extended-release or delayed-release formulation, we are not aware of any specific concerns with crushing it prior to administration.

We encourage you to report any adverse events occurring in connection with the use of oxycodone and acetaminophen tablets by calling 1-800-778-7898. Alternatively, this information may be reported to the FDA's Med Watch Reporting System by phone at 1-800-FDA-1088, by facsimile at 1-800-FDA-0178, or by mail using Form 3500 available at <http://www.fda.gov/medwatch/index.html>.

I hope this information has been useful to you. Please be advised that we are solely providing this information per your request, and do not recommend the use of oxycodone and acetaminophen tablets outside of its approved indication(s). Patient safety is our highest priority at Mallinckrodt and we are committed to improving the health and well-being of patients around the world. Please carefully review this information and contact Mallinckrodt if you should have any questions about its safe and effective use.

Best Regards,

Senior Medical Information Specialist  
Medical Affairs Department  
1-800-778-7898

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**References**

1. Oxycodone and acetaminophen tablets USP [package insert]. Hazelwood, MO: Mallinckrodt Pharmaceuticals; 2014.

The enclosed information is supplied as a professional courtesy in response to your inquiry. It is intended to provide pertinent data to assist you in forming your own conclusions and making decisions. The information is not intended to advocate any indication, dosage, or other claim that is not covered in the package insert. Current prescribing information documents can be accessed through our web site at [www.Mallinckrodt.com](http://www.Mallinckrodt.com). For questions or concerns, please contact the Medical Affairs Department at the number listed above.