

# Covidien Launches EXALGO(TM) Extended-Release Tablets

Covidien

### ***New extended-release formulation available for around-the-clock pain management***

ST. LOUIS, Apr 26, 2010 (BUSINESS WIRE) --Covidien (NYSE: COV), a leading global provider of healthcare products, today introduced EXALGO(TM) (hydromorphone HCl) Extended-Release Tablets, (CII), the only extended-release hydromorphone treatment available in the United States. This proven therapy, combined with an innovative delivery system, provides opioid-tolerant patients suffering from moderate-to-severe chronic pain relief for 24 hours per dose.

Approved by the U.S. Food and Drug Administration (FDA) on March 1, 2010, EXALGO tablets provide a well-known therapy in hydromorphone HCl - used in the treatment of chronic pain for more than 80 years. The indication for EXALGO is once-daily administration for the management of moderate-to-severe pain in opioid-tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time. EXALGO is available in 8 mg, 12 mg and 16 mg tablets.

"Chronic pain patients experience pain so severe it can often be crippling," said noted pain treatment expert, Dr. Lynn Webster, Medical Director of Lifetree Clinical Research and Pain Clinic in Salt Lake City, Utah. "This pain can make it almost impossible for patients to hold a job, or to do simple activities, such as going to the grocery store or taking their child to soccer practice. Extended-release formulations like EXALGO can help make daily pain more manageable by avoiding the peaks and troughs of pain that can occur with short-acting opioids."

Currently there is an unmet need for longer-lasting treatments to manage chronic pain. In the 2006 American Pain Foundation's *Voices of Chronic Pain Survey*, only 23 percent of chronic pain patients reported their medications were "very effective."<sup>1</sup> Historically, patients who suffered from chronic pain may have been prescribed short-acting opioids or some other extended-release opioids, which would have caused them to take multiple doses of their pain medication over the course of one day.

"As the largest supplier of generic controlled pain medications in the United States, based on number of prescriptions, Covidien is focused on providing patients with access to advanced medications that expand the limits of pain therapy by combining proven drugs with innovative delivery systems," said Timothy R. Wright, President, Pharmaceuticals, Covidien. "With the launch of EXALGO tablets, opioid-tolerant chronic pain patients will be given the option to take one dose each day that provides 24 hours of relief and keeps pain waiting. This is a breakthrough for pain management."

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EXALGO utilizes the OROS<sup>(R)</sup> Push-Pull(TM) osmotic delivery system designed to release the opioid at a controlled rate. By providing a steady release of hydromorphone throughout the day, the drug is formulated to help minimize the peaks and troughs that are sometimes experienced by chronic pain patients who rely on products that are dosed at more frequent intervals to deliver pain relief.

With the addition of extended-release opioids to the pain treatment landscape, physicians have another tool to help patients manage what is often debilitating moderate-to-severe chronic pain.

The launch of EXALGO tablets includes a comprehensive Risk Evaluation and Mitigation Strategy (REMS) program that is designed to assure the safe use of EXALGO. The REMS program for EXALGO includes a medication guide and a robust set of educational programs and materials. Covidien's focused effort to help ensure that prescribers, pharmacists and patients have the needed information regarding appropriate prescribing, dispensing and use of EXALGO tablets will be an important piece of the EXALGO REMS program. Under the program, healthcare provider education is required as an important element to assure safe use, with a focus on appropriate patient selection and dosing. There is no restricted distribution network for EXALGO, and no requirement for physicians, pharmacists or patients to enroll in a registry in order to access the product.

As part of Covidien's ongoing commitment to be a responsible advocate for patients, the Company also has developed a broad range of voluntary safe-use tools for EXALGO that will be provided to healthcare professionals, pharmacists, patients and caregivers. These materials include a patient/prescriber medication agreement, patient counseling guide and additional safe-use tools. All materials will be continually reviewed and updated based on feedback from patients and prescribers.

For more information about EXALGO, log on to [www.keppainwaiting.com](http://www.keppainwaiting.com) [1].

### **IMPORTANT RISK INFORMATION**

#### **WARNING: POTENTIAL FOR ABUSE, IMPORTANCE OF PROPER PATIENT**

#### **SELECTION AND LIMITATIONS OF USE**

##### **Potential for Abuse**

**EXALGO contains hydromorphone, an opioid agonist and a Schedule II controlled substance with an abuse liability similar to other opioid analgesics. EXALGO can be abused in a manner similar to other opioid agonists, legal or illicit. These risks should be considered when administering, prescribing or dispensing EXALGO in situations where the healthcare professional is concerned about increased risk of misuse, abuse or diversion. Schedule II opioid substances, which include hydromorphone, morphine, oxycodone, fentanyl, oxymorphone and methadone, have the highest potential for abuse and risk of fatal overdose due to respiratory depression.**

## **Proper Patient Selection**

**EXALGO is an extended-release formulation of hydromorphone hydrochloride indicated for the management of moderate-to-severe pain in opioid tolerant patients when a continuous around-the-clock opioid analgesic is needed for an extended period of time. Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day or an equianalgesic dose of another opioid, for a week or longer.**

**EXALGO is for use in opioid-tolerant patients only.**

**Fatal respiratory depression could occur in patients who are not opioid tolerant.**

**Accidental consumption of EXALGO, especially in children, can result in a fatal overdose of hydromorphone.**

## **Limitations of Use**

**EXALGO is not indicated for the management of acute or postoperative pain.**

**EXALGO is not intended for use as an as-needed analgesic.**

**EXALGO tablets are to be swallowed whole and are not to be broken, chewed, dissolved, crushed or injected. Taking broken, chewed, dissolved or crushed EXALGO or its contents leads to rapid release and absorption of a potentially fatal dose of hydromorphone.**

- EXALGO is also contraindicated in patients who:
  - need management of mild pain or pain not expected to persist
  - have significant impaired respiratory function including those with acute or severe bronchial asthma or hypercarbia.
  - have or are suspected to have paralytic ileus
  - have narrowed or obstructed gastrointestinal (GI) tract including those resulting from previous surgery or "blind loops" in the GI tract
  - have known hypersensitivity to any components including hydromorphone hydrochloride and sulfites
- Avoid concurrent use of alcohol and EXALGO. Concurrent use of EXALGO with central nervous system (CNS) depressants, including alcohol, increases risk of respiratory depression, hypotension, and profound sedation,

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potentially resulting in coma or death. EXALGO may impair the ability to drive a car or operate machinery.

- Not intended for use in patients who have received monoamine oxidase (MAO) inhibitors within 14 days of starting EXALGO.
- Use with caution and in reduced doses in older or debilitated patients, as well as patients with renal or hepatic insufficiency, Addison's disease, delirium tremens, myxedema or hypothyroidism, prosthetic hypertrophy or urethral stricture, toxic psychosis. May aggravate convulsions in patients with convulsive disorders; may induce or aggravate seizures in some clinical settings. Consider use of an alternate analgesic in patients with severe renal impairment.
- Respiratory depression, which occurs more frequently in elderly or debilitated patients, is the chief hazard with EXALGO.
- Most common adverse events (>10%) seen in clinical studies (N=2474) were: constipation (31%), nausea (28%), vomiting, somnolence, headache, asthenia and dizziness. Serious adverse events could also include head injury, hypotensive effects, GI effects, cardiac arrest from overdose and precipitation of withdrawal.
- Use EXALGO with extreme caution in patients susceptible to intracranial effects of CO<sub>2</sub> retention.
- Do not abruptly discontinue EXALGO.

**See Full Prescribing Information for additional Important Risk Information at [http://www.exalgo.com/media/pdf/EXALGO\\_FullPrescribingInformation.pdf](http://www.exalgo.com/media/pdf/EXALGO_FullPrescribingInformation.pdf) [2]**

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OROS and Push-Pull are trademarks of ALZA Corporation.

### About Covidien

Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies. With 2009 revenue of \$10.7 billion, Covidien has 42,000 employees worldwide in more than 60 countries, and its products are sold in over 140 countries. Please visit [www.covidien.com](http://www.covidien.com) [3] to learn more about our business.

<sup>1</sup> Voices of Chronic Pain Survey, The American Pain Foundation. May 2006.

[SOURCE](#) [4]

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[3] [http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.covidien.com&esheet=6263580&lan=en\\_US&anchor=www.covidien.com&index=3&md5=ffb1c75800c622b2dc9e89d7ddb40cb](http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.covidien.com&esheet=6263580&lan=en_US&anchor=www.covidien.com&index=3&md5=ffb1c75800c622b2dc9e89d7ddb40cb)

[4] <http://investor.covidien.com/phoenix.zhtml?c=207592&p=RssLanding&cat=news&id=1417551>