EXALGO®
(hydromorphone HCl) CII
Extended-Release Tablets

You are cordially invited to attend a presentation discussing

EXALGO® — Important Considerations in Customizing Pain Management: Patient Selection and Dosing Strategies

Ellen M Battista, DNS, ANP, PNP

April 11, 2013

6:30 PM

Del Monte Lodge Renaissance

41 N Main Street

Pittsford, NY 14534

Please RSVP to your Covidien Representative

Warren Klein 716/536-3261

Or Register at http://reg.pharmethod.com/covidien with Program ID 12965

This event is promotional; there are no certified continuing medical educational credits approved for this presentation.

Covidien proudly adheres to the Pharmaceutical Research and Manufacturers Association Code for Interactions with Healthcare Professionals. Attendance must be limited strictly to healthcare professionals. Spouses and other guests cannot be accommodated. Thank You.

IMPORTANT RISK INFORMATION

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE
See full prescribing information for complete boxed warning.

- **EXALGO® contains hydromorphone, a Schedule II controlled substance. Monitor for signs of misuse, abuse, and addiction during EXALGO therapy.**
- **Fatal respiratory depression may occur, with highest risk at initiation and with dose increases; instruct patients on proper administration of EXALGO tablets to reduce risk. EXALGO is for use in opioid-tolerant patients only. Crushing, dissolving, or chewing the tablet can cause rapid release and absorption of a potentially fatal dose of hydromorphone.**
- **Accidental ingestion of EXALGO can result in fatal overdose of hydromorphone, especially in children.**

See Important Risk Information, including full boxed warning on next page, and accompanying Full Prescribing Information.

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INDICATION

EXALGO® (hydromorphone HCl) Extended-Release Tablets (CII) is indicated 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.

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Abuse Potential

EXALGO contains hydromorphone, an opioid agonist and a Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit. Assess each patient's risk for opioid abuse or addiction prior to prescribing EXALGO. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depressive disorder). Routinely monitor all patients receiving EXALGO for signs of misuse, abuse, and addiction during treatment.

Life-threatening Respiratory Depression

Respiratory depression, including fatal cases, may occur with use of EXALGO, even when the drug has been used as recommended and not misused or abused. EXALGO is for use in opioid tolerant patients only. Proper dosing and titration are essential and EXALGO should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation of EXALGO or following a dose increase. Crushing, dissolving, or chewing the tablet can cause rapid release and absorption of a potentially fatal dose of hydromorphone.

Accidental Exposure

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

- EXALGO is contraindicated in:
  - Opioid non-tolerant patients. Fatal respiratory depression could occur in patients who are not opioid tolerant.
  - Patients with significant respiratory depression
  - Patients with acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
  - Patients with known or suspected paralytic ileus
  - Patients who have had surgical procedures and/or underlying disease resulting in narrowing of the gastrointestinal tract, or have "blind loops" of the gastrointestinal tract or gastrointestinal obstruction
  - Patients with hypersensitivity (e.g., anaphylaxis) to hydromorphone or sulfite-containing medications
- EXALGO is indicated for opioid tolerant patients only. 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 not intended for use as an as-needed analgesic and is not indicated for the management of acute or postoperative pain. It is contraindicated in patients who need management of mild pain or pain not expected to persist.
- Avoid concurrent use of alcohol and EXALGO. Concurrent use of EXALGO with CNS depressants, including alcohol, increases risk of respiratory depression, hypotension, and profound sedation, potentially resulting in coma or death. EXALGO may impair the ability to drive a car or operate machinery.
- Not intended in patients who have received 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, prostatic 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.
- Serious adverse events could also include hypotensive effects, GI effects, cardiac arrest from overdose and precipitation of withdrawal. Most common adverse events (>10%) seen in clinical studies (N=2474) were: constipation (31%), nausea (28%), vomiting, somnolence, headache, asthenia and dizziness.
- Use EXALGO with extreme caution in patients susceptible to intracranial effects of CO_2 retention.
- Do not abruptly discontinue EXALGO.

See Full Prescribing Information and Medication Guide attached.