

INDICATION

EXALGO® tablets are an extended release oral formulation of the opioid agonist hydromorphone hydrochloride that is indicated for 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.

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 tract including those 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 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 CO₂ retention.
- Do not abruptly discontinue EXALGO