Exalgo (hydromorphone hydrochloride) - Drug Summary

Mallinckrodt, Inc.

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BOXED WARNING

Exposes patients and other users to the risks of opioid addiction, abuse, and misuse, potentially leading to overdose and death; assess each patient's risk prior to prescribing, and monitor regularly for development of these behaviors/conditions. Serious, life-threatening, or fatal respiratory depression may occur; monitor for occurrence, especially during initiation or following a dose increase. Crushing, dissolving, or chewing tabs can cause rapid release and absorption of potentially fatal dose; instruct to swallow tabs whole. Accidental ingestion, especially in children, can result in a fatal overdose. Prolonged use during pregnancy can result in neonatal opioid withdrawal syndrome.

THERAPEUTIC CLASS

Opioid analgesic

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Severe Pain (Daily, Around-the-Clock Management)

Opioid-Tolerant:
>17 Years:
D/C or taper all other extended-release opioids

From Other Oral Hydromorphone Formulations:
Initial: Administer starting dose equivalent to patient's total daily oral hydromorphone dose, given once daily

From Other Oral Opioids:
Initial: 50% of the calculated estimate of daily hydromorphone requirement using the appropriate conversion factor

On a Single Opioid: Sum the current total daily dose of the opioid, then multiply the total daily dose by the conversion factor to calculate the approx oral hydromorphone daily dose
On Regimen of >1 Opioid: Calculate the approx oral hydromorphone dose for each opioid and sum the totals to obtain the approx total hydromorphone daily dose
On Regimen of Fixed-Ratio Opioid/Nonopioid Analgesic Products: Use only the opioid component of these products in the conversion

Approx Oral Conversion Factor:
Always round the dose down, if necessary to appropriate strengths available
Hydromorphone: 1
Codeine: 0.06
Hydrocodone: 0.4
Methadone: 0.6
Morphine: 0.2
Oxycodone: 0.4
Oxymorphone: 0.6

Close observation and frequent titration are warranted until pain management is stable on the new opioid

From Transdermal Fentanyl:
Initiate treatment 18 hrs following removal of transdermal fentanyl patch
Calculate 24-hr hydromorphone dose by using a conversion factor of 25mcg/hr fentanyl transdermal patch to 12mg of hydromorphone, then reduce dose by 50%

DOSING CONSIDERATIONS

Renal Impairment
Moderate: Start w/ 50% of dose
Severe: Start w/ 25% of dose; consider use of an alternate analgesic that may permit more flexibility w/ dosing interval
Closely monitor for respiratory and CNS depression during initiation and dose titration

Hepatic Impairment
Moderate: Start w/ 25% of dose; closely monitor for respiratory and CNS depression during initiation and dose titration
Severe: Use of alternate analgesics is recommended

Discontinuation
Taper dose gradually by 25-50% every 2-3 days down to a dose of 8mg before discontinuation of therapy to prevent signs and symptoms of withdrawal

ADMINISTRATION

Oral route

Swallow tabs whole; do not crush, dissolve, or chew
May be administered w/o regard to meals

Disposal
Flush all remaining tabs down the toilet or remit to authorities at a certified drug take-back program

HOW SUPPLIED

Tab, Extended-Release (ER): 8mg, 12mg, 16mg, 32mg

CONTRAINDICATIONS

Opioid nontolerant patients, significant respiratory depression, acute or severe bronchial asthma in unmonitored settings or in the absence of resuscitative equipment, known or suspected paralytic ileus, previous surgical procedures and/or underlying disease resulting in narrowing of the GI tract, or "blind loops" of the GI tract or GI obstruction.

WARNINGS/PRECAUTIONS

Reserve use in patients for whom alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Should only be prescribed by healthcare professionals knowledgeable in the use of potent opioids for the management of chronic pain. Do not begin as the 1st opioid. Not indicated as a PRN analgesic. Overestimating the dose when converting from another opioid product may result in fatal overdose with the 1st dose. Life-threatening respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients. Consider alternative nonopioid analgesics in patients with significant chronic obstructive pulmonary disease (COPD) or cor pulmonale, and in patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or preexisting respiratory depression. May cause severe hypotension including orthostatic hypotension and syncope in ambulatory patients; increased risk in patients whose ability to maintain BP has already been compromised. Monitor for signs of sedation and respiratory depression in patients who may be susceptible to the intracranial effects of carbon dioxide retention (eg, those with increased intracranial pressure [ICP] or brain tumors). May obscure clinical course in patients with head injury. Avoid with impaired consciousness or coma. May cause spasm of the sphincter of Oddi; monitor for worsening of symptoms in patients with biliary tract disease, including acute pancreatitis. Contains sodium metabisulfite; may cause allergic-type reactions in certain susceptible people. May aggravate convulsions with convulsive disorders, and may induce or aggravate seizures; monitor for worsened seizure control in patients with history of seizure disorders. Avoid abrupt discontinuation; taper dose gradually. May impair mental/physical abilities. Not for use during and immediately prior to labor. Caution in elderly.

ADVERSE REACTIONS

Respiratory depression, constipation, N/V, somnolence, headache, asthenia, dizziness, diarrhea, pruritus, insomnia, anorexia, hyperhidrosis, dry mouth, peripheral edema, abdominal pain.

DRUG INTERACTIONS

Concomitant use with alcohol and other CNS depressants (eg, sedatives, hypnotics, neuroleptics, general anesthetics) may increase the risk of respiratory depression, hypotension, profound sedation, coma, and death; reduce dose of one or both drugs when combined therapy is considered. Monitor elderly, cachectic, and debilitated patients closely when coadministered with other drugs that depress respiration. Mixed agonist/antagonist (eg, pentazocine, nalbuphine, butorphanol) and partial agonist (eg, buprenorphine) analgesics may reduce the analgesic effect or precipitate withdrawal symptoms; avoid coadministration. Not recommended for use in patients who have received MAOIs within 14 days; if concurrent therapy is unavoidable, monitor patients for increased respiratory and CNS depression. Anticholinergics or other medications with anticholinergic activity may increase risk of urinary retention and/or severe constipation, which may lead to paralytic ileus.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Opioid analgesic; has not been established. Thought to be mediated through opioid-specific receptors located predominantly in the CNS.

PHARMACOKINETICS

Absorption: Administration of variable doses resulted in different parameters. **Distribution:** Plasma protein

binding (27%); (IV) V_d=2.9L/kg; crosses placenta, found in breast milk. **Metabolism:** Liver (extensive) via glucuronidation; hydromorphone-3-glucuronide (metabolite). **Elimination:** Urine (75%, 7% unchanged), feces (1% unchanged); $T_{1/2}$ varies based on dosing; refer to PI for further information.

ASSESSMENT

Assess for abuse/addiction risk, opioid tolerance, prior opioid therapy, drug hypersensitivity, increased ICP, brain tumor, respiratory depression, COPD or other respiratory complications, GI obstruction, paralytic ileus, history of seizures, renal/hepatic impairment, pregnancy/nursing status, possible drug interactions, and any other conditions where treatment is contraindicated or cautioned.

MONITORING

Monitor for signs/symptoms of respiratory depression (especially within first 24-72 hrs of initiation), physical dependence, tolerance, hypotension, syncope, aggravation/induction of seizures, symptoms of worsening biliary tract disease, mental/physical impairment, and other adverse reactions. Routinely monitor for signs of addiction, abuse, or misuse. Periodically reassess the continued need for therapy.

PATIENT COUNSELING

Inform that use of drug may result in addiction, abuse, and misuse; instruct not to share with others and to take steps to protect from theft or misuse. Inform of the risk of life-threatening respiratory depression; advise how to recognize respiratory depression and to seek medical attention if experiencing breathing difficulties. Inform that accidental ingestion, especially in children, may result in respiratory depression or death; instruct to store securely and dispose unused tab by flushing down the toilet. Inform female patients of reproductive potential that prolonged use of drug during pregnancy may result in neonatal opioid withdrawal syndrome and instruct to inform physician if pregnant or planning to become pregnant. Inform that potentially serious additive effects may occur if drug is used with alcohol or other CNS depressants, and advise not to use such drugs unless supervised by a healthcare provider. Inform of the proper administration instructions. Advise that patients with certain stomach or intestinal problems may be at higher risk of developing a blockage; instruct to contact healthcare provider immediately if symptoms develop. Inform that drug may cause orthostatic hypotension and syncope; instruct how to recognize symptoms of low BP and how to reduce the risk of serious consequences should hypotension occur. Inform that drug may impair the ability to perform potentially hazardous activities; advise not to perform such tasks until they know how they will react to the medication. Advise of potential for severe constipation, including management instructions. Advise how to recognize anaphylaxis and when to seek medical attention.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F).

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