FIRST TIME GENERIC APPROVAL

Brand Name	Hysingla ER®
Generic Name	hydrocodone bitartrate
Drug Manufacturer	Alvogen Pine Brook, LLC.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

March 01, 2021

LAUNCH DATE

March 04, 2021

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 208269

DISPENSING RESTRICTIONS

Open

Overview

INDICATION FOR USE

For the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use:

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve hydrocodone bitartrate for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Hydrocodone bitartrate is not indicated as an as-needed (prn) analgesic.

MECHANISMS OF ACTION

Hydrocodone is a full opioid agonist with relative selectivity for the mu-opioid receptor, although it can interact with other opioid receptors at higher doses. The principal therapeutic action of hydrocodone is analgesia. Like all full opioid agonists, there is no ceiling effect for analgesia with hydrocodone. Clinically, dosage is titrated to provide adequate analgesia and may be limited by adverse reactions, including respiratory and CNS depression. The precise mechanism of the analgesic action is unknown. However, specific CNS opioid receptors for endogenous compounds with opioid-like activity have been identified throughout the brain and spinal cord and are thought to play a role in the analgesic effects of this drug.

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DOSE FORM AND STRENGTH

Extended-release oral tablets: 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, and 120 mg

DOSE & ADMINISTRATION

- To be prescribed only by healthcare providers knowledgeable in use of potent opioids for management of chronic pain.
- Daily doses of hydrocodone bitartrate extended-release tablets greater than or equal to 80 mg are only for use in patients in whom tolerance to an opioid of comparable potency has been established.
- Patients considered opioid-tolerant are those taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid.
- Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.
- Individualize dosing based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse.
- Instruct patients to swallow hydrocodone bitartrate extended-release tablets intact, and not to crush, chew, or dissolve the tablets (risk of potentially fatal overdose).
- Instruct patients to take tablets one at a time, with enough water to ensure complete swallowing immediately after placing in the mouth.
- Discuss availability of naloxone with the patient and caregiver and assess each patient's need for access to naloxone, both when initiating and renewing treatment with hydrocodone bitartrate extended-release tablets. Consider prescribing naloxone based on the patient's risk factors for overdose.
- For opioid-naïve patients, initiate with 20 mg tablets orally every 24 hours.
- To convert to hydrocodone bitartrate extended-release tablets from another opioid, follow the conversion instructions to obtain an estimated dose.
- Dose titration of hydrocodone bitartrate extended-release tablets may occur every 3 to 5 days.
- Patients with Severe Hepatic Impairment: Initiate dosing with one half of the recommended starting dosage and titrate carefully. Monitor for respiratory depression, sedation, and hypotension.
- Patients with Moderate to Severe Renal Impairment and End-Stage Renal Disease: Initiate dosing at one half the recommended starting dosage and titrate carefully. Monitor for signs of respiratory depression, sedation, and hypotension.
- Do not abruptly discontinue hydrocodone bitartrate extended-release tablets in a physically dependent patient because rapid discontinuation of opioid analgesics has resulted in serious withdrawal symptoms, uncontrolled pain, and suicide.