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Dosing and Administration • Available in 8 mg, 12 mg, 16 mg, and 32 mg tablet strengths

• The safe conversion from another opioid therapy to EXAFERIN requires appropriate dosing and administration. Administer the starting dose once-daily



Treatment for: Pain in Opioid Tolerant Patients • Titrate no more frequently than every 3 to 4 days until adequate pain relief with tolerable side effects has been achieved - 24 mg EXAFERIN / 2 = 12 mg EXAFERIN on

EXAFERIN® (hydromorphone HCI) () Extended-Release Tablets Once Daily

EXAFERIN ® (hydromorphone) is an opioid pain medication. An opioid is sometimes called a narcotic. EXAFERIN extended-release tablets are used to treat moderate to severe pain.

EXAFERIN extended-release tablets are for around-the-clock treatment of moderate to severe pain. It is not for use on an as-needed basis for pain.

INDICATION

EXAFERIN® (hydromorphone HCI) 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.

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE Abuse Potential

EXAFERIN 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 EXAFERIN. 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 EXAFERIN for signs of misuse, abuse, and addiction during treatment.

EXAFERIN 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.

EXAFERIN 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.

Use EXAFERIN with extreme caution in patients susceptible to intracranial effects of CO2 retention.

Do not abruptly discontinue EXAFERIN

SET expectations

There is no immediate-release component; plasma levels rise for the first 6 to 8 hours after the initial dose.

It takes 3 to 4 days to reach steady state.

Prescribe supplemental pain medication to help your patients get to steady state, through titration, and as needed thereafter.

Food and Drug Administration (FDA) approved .Prescription Only (POM)

A Taj Pharma"India Product