

FIRST TIME GENERIC APPROVAL

Brand Name	Zohydro® ER
Generic Name	hydrocodone bitartrate ER capsule
Drug Manufacturer	Alvogen Malta Operations Ltd.

New Drug Approval

Dosage form(s): 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg Capsules

Therapeutic equivalent code: AB

FDA Approval Date: January 21, 2020

Indications for Use

hydrocodone bitartrate extended-release capsules is indicated 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

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