

Hysingla[™] ER (hydrocodone bitartrate) – First-time generic

- On March 4, 2021, Alvogen launched an <u>AB-rated</u> generic version of Purdue Pharma's <u>Hysingla ER</u> (hydrocodone) extended-release tablets.
- Hysingla ER is approved for the management of pain severe enough to require daily, around-theclock, long-term opioid treatment and for which alternative treatment options are inadequate.
- Hydrocodone bitartrate is available generically as an <u>extended-release capsule</u>. Hydrocodone bitartrate is available generically in combination with acetaminophen as a <u>tablet</u> and <u>oral solution</u> and in combination with ibuprofen as a <u>tablet</u>.
- Hydrocodone bitartrate extended-release capsules, hydrocodone bitartrate/acetaminophen and hydrocodone bitartrate/ibuprofen carry a similar indication as Hysingla ER.
- In addition, hydrocodone bitartrate is also available generically in combination with other products for the treatment of cough and cold symptoms.
- Hysingla ER carries a boxed warning for addiction, abuse, and misuse; risk evaluation and mitigation strategy (REMS); life-threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; cytochrome P450 3A4 interaction; and risks from concomitant use with benzodiazepines or other central nervous system depressants.



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