USE AND IMPORTANT SAFETY INFORMATION¹

USE¹
VICODIN® 5 mg/300 mg, VICODIN ES® 7.5 mg/300 mg, and VICODIN HP® 10 mg/300 mg (hydrocodone bitartrate and acetaminophen) tablets, USP are used for the relief of moderate to moderately severe pain. VICODIN, VICODIN ES, and VICODIN HP contain two different ingredients: hydrocodone (an opioid pain medicine) and acetaminophen (a non-aspirin pain medicine).

IMPORTANT SAFETY INFORMATION¹

Warning for liver damage: One ingredient in this product is acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product.

- VICODIN, VICODIN ES, and VICODIN HP should not be used if you are allergic to hydrocodone or acetaminophen. Tell your healthcare provider if you are allergic to any other opioid pain medicine before taking this drug, as you may exhibit cross-sensitivity to hydrocodone.

- Rarely, one ingredient in VICODIN, VICODIN ES, and VICODIN HP, acetaminophen, may cause serious skin reactions, such as acute generalized exanthematous pustulosis, Stevens-Johnson syndrome, and toxic epidermal necrolysis. These reactions may develop at any point after use, whether after one time or long-term use, and can be fatal. If you get serious skin reactions or a skin rash, especially with blisters and a fever, immediately contact your healthcare provider. VICODIN, VICODIN ES, and VICODIN HP should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

- VICODIN, VICODIN ES, and VICODIN HP should not be used if you have breathing problems or a blocked bowel. These drugs can cause breathing problems at high doses or in sensitive patients. Talk with your healthcare provider if you have had a recent head injury, if your breathing slows down, or if you feel faint, dizzy, or confused. If you have trouble breathing, or your face or throat swells, immediately contact your healthcare provider.

- One ingredient in VICODIN, VICODIN ES, and VICODIN HP is hydrocodone, a controlled substance that can be habit-forming and/or abused. You should take this drug only for the condition for which it is prescribed, for as long as it is prescribed, in the amount prescribed, and no more frequently than prescribed. Do not give this drug to others, even if they have similar symptoms. Unused tablets should be thrown away with household waste.

- Taking VICODIN, VICODIN ES, and VICODIN HP can make you drowsy and impair your ability to drive a car, operate machinery, or perform other potentially dangerous activities. Do not drive or operate heavy machinery until you know how you react to this medicine.
VICODIN, VICODIN ES, and VICODIN HP should be used with caution if you are elderly or disabled, or if you have any of the following medical conditions: heart, liver, or kidney problems; adrenal or thyroid gland problems; enlarged prostate or difficulty urinating; lung disease; difficulty swallowing; stomach problems; or current or past problems with alcohol and drug abuse.

Avoid taking VICODIN, VICODIN ES, and VICODIN HP with alcohol or other depressants. To avoid possible serious drug interactions, be sure to tell your healthcare provider about all prescription and non-prescription medicines, vitamins, and herbal supplements you take. Also tell your healthcare provider if you are already using medicines to treat depression or allergic reactions, other pain medicines, or medicines that make you sleepy, including those to treat anxiety or seizures, or for muscle relaxation.

VICODIN, VICODIN ES, and VICODIN HP contain acetaminophen, an ingredient in many other prescription and non-prescription medicines. Do not take other medicines containing acetaminophen unless your healthcare provider recommends it. Taking too much acetaminophen can be harmful to your liver.

Do not take VICODIN, VICODIN ES, or VICODIN HP if you are pregnant or plan to become pregnant, unless you are directed to do so by your healthcare provider. Drug dependence and breathing problems have occurred in newborns when the mother has taken this drug before delivery.

If you are breast-feeding (nursing), you should be aware that the medicines in VICODIN, VICODIN ES, and VICODIN HP might pass into your breast milk. Ask your healthcare provider for advice before taking any medicine while breast-feeding.

If you stop taking VICODIN, VICODIN ES, or VICODIN HP suddenly after taking it for a few days to weeks, you may experience signs of withdrawal, such as irritability, sweating, racing heart, and faster breathing. Contact your healthcare provider if you experience these withdrawal signs to learn how to safely stop taking this medication.

Keep VICODIN, VICODIN ES, and VICODIN HP out of the reach of children and keep your tablets in a secure place where they will not be stolen.

If you take too much VICODIN, VICODIN ES, or VICODIN HP or overdose, call your local emergency or poison control center right away.

The most common side effects of VICODIN, VICODIN ES, and VICODIN HP are lightheadedness, dizziness, drowsiness, nausea, vomiting, and constipation.

Please see Full Prescribing Information (/prescribing-information), including Important WARNING, for Vicodin formulations and discuss with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088 (1-800-332-1088).

If you cannot afford your medication, visit www.pparx.org for assistance.

Reference: 1. VICODIN, VICODIN ES, VICODIN HP 5, 7.5, 10 mg (hydrocodone)/300 mg (acetaminophen) [package insert].

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Patient Site (/patient)