SAFETY CONSIDERATIONS

HEPATOTOXICITY: ACETAMINOPHEN HAS BEEN ASSOCIATED WITH CASES OF ACUTE LIVER FAILURE, AT TIMES RESULTING IN LIVER TRANSPLANT AND DEATH. MOST CASES OF LIVER INJURY ARE ASSOCIATED WITH DOSES THAT EXCEED 4000 MG/DAY.

VICODIN, VICODIN ES, and VICODIN HP tablets are contraindicated in patients who have hypersensitivity to the drugs or their inactive ingredients. VICODIN formulations contain hydrocodone which is an opioid agonist and a schedule III controlled substance with an abuse liability and dependence. It may cause dose-related respiratory depression in sensitive patients and caution should be exercised when prescribing to elderly or debilitated patients. The concomitant use with other central nervous system (CNS) depressants and monoamine oxidase (MAO) inhibitors or tricyclic antidepressants may increase the effect of either drug. Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent.

INDICATION

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) tablets are indicated for the relief of moderate to moderately severe pain.

ABBVIE’S VICODIN IS A GENERIC PRODUCT WITH 300 MG OF ACETAMINOPHEN

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For additional information, visit vicodin.com.

Please see additional Important Safety Information, including BOXED WARNING on hepatotoxicity, on page 2.

Please click here for Full Prescribing Information.
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IMPORTANT SAFETY INFORMATION
BOXED WARNING
HEPATOTOXICITY: 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.

CONTRAINDICATIONS
VICODIN, VICODIN ES, and VICODIN HP tablets are contraindicated in patients previously exhibiting hypersensitivity to hydrocodone or acetaminophen, and also in patients known to be hypersensitive to other opioids, as they may exhibit cross-sensitivity to hydrocodone.

WARNINGS
Controlled Substance: VICODIN, VICODIN ES, and VICODIN HP contain hydrocodone, which is an opioid agonist and a Schedule III controlled substance with an abuse liability.

Abuse and Dependence: VICODIN, VICODIN ES, and VICODIN HP can be abused in a manner similar to other opioid agonists, legal or illicit. Psychological dependence, physical dependence, and tolerance may develop upon repeated administration of narcotics; therefore, these products should be prescribed and administered with caution.

Hypersensitivity/Anaphylaxis: There have been post-marketing reports of hypersensitivity and anaphylaxis associated with use of acetaminophen.

Respiratory Depression: At high doses or in sensitive patients, hydrocodone may produce dose-related respiratory depression.

Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury or other intracranial pressure.

Acute Abdominal Conditions: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

PRECAUTIONS
As with any narcotic, special caution should be used when prescribing hydrocodone to elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison’s disease, prostatic hypertrophy, or urethral stricture. Caution should also be exercised with patients who are likely to take other acetaminophen-containing medications, antihistamines, antipsychotics, anti-anxiety agents, other narcotic analgesics, or other central nervous system (CNS) depressants (including alcohol) concomitantly. When combined therapy is contemplated, the dose of one or both agents should be reduced. Hydrocodone, like all narcotics, may impair mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a car or operating machinery.

The use of monoamine oxidase (MAO) inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone.

VICODIN, VICODIN ES, and VICODIN HP tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. Administration to the mother during labor or shortly before delivery may result in some degree of respiratory depression in the newborn.

ADVERSE REACTIONS
The most frequently reported adverse reactions include lightheadedness, dizziness, sedation, nausea, and vomiting. Prolonged administration may produce constipation.

DOSAGE AND ADMINISTRATION
• VICODIN 5 mg/300 mg: The usual adult dosage is one or two tablets every four to six hours as needed for pain. The total daily dosage should not exceed 8 tablets.
• VICODIN ES 7.5 mg/300 mg: The usual adult dosage is one tablet every four to six hours as needed for pain. The total daily dosage should not exceed 6 tablets.
• VICODIN HP 10 mg/300 mg: The usual adult dosage is one tablet every four to six hours as needed for pain. The total daily dosage should not exceed 6 tablets.

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

For additional information, visit vicodin.com.
Please click here for Full Prescribing Information.