

Lorcet® 10/650

Each tablet contains: 10 mg hydrocodone bitartrate (Warning: May be habit-forming) and 650 mg acetaminophen.

Reference:

1. Data on file, Forest Laboratories, New York, NY.

INDICATIONS AND USAGE: For the relief of moderate to moderately severe pain.
CONTRAINDICATIONS: Hypersensitivity to acetaminophen or hydrocodone.
WARNINGS: Respiratory Depression: At high doses or in sensitive patients, hydrocodone may produce dose-related respiratory depression by acting directly on the brain stem respiratory center. Hydrocodone also affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing.
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, other intracranial lesions or a preexisting increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.
Acute Abdominal Conditions: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.
PRECAUTIONS: Special Risk Patients: As with any narcotic analgesic agent, Lorcet® 10/650 should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture. The usual precautions should be observed and the possibility of respiratory depression should be kept in mind.
Cough Reflex: Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when Lorcet® 10/650 is used postoperatively and in patients with pulmonary disease.
Drug Interactions: Patients receiving other narcotic analgesics, antipsychotics, anti-anxiety agents, or other CNS depressants (including alcohol) concomitantly with Lorcet® 10/650 may exhibit an additive CNS depression. When combined therapy is contemplated, the dose of one or both agents should be reduced. The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus.
Usage in Pregnancy: Teratogenic Effects: Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. Lorcet® 10/650 should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting, and fever. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose. There is no consensus on the best method of managing withdrawal. Chlorpromazine 0.7 to 1 mg/kg q6h, and paregoric 2 to 4 drops/kg q4h, have been used to treat withdrawal symptoms in infants. The duration of therapy is 4 to 28 days, with the dosage decreased as tolerated.
Labor and Delivery: As with all narcotics, administration of Lorcet® 10/650 to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.
Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Lorcet® 10/650, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Pediatric Use: Safety and effectiveness in children have not been established.
ADVERSE REACTIONS: The most frequently observed adverse reactions include lightheadedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients and some of these adverse reactions may be alleviated if the patient lies down. Other adverse reactions include:
Central Nervous System: Drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, psychic dependence, mood changes.
Gastrointestinal System: The antiemetic phenothiazines are useful in suppressing the nausea and vomiting which may occur (see above); however, some phenothiazine derivatives seem to be antianalgesic and to increase the amount of narcotic required to produce pain relief, while other phenothiazines reduce the amount of narcotic required to produce a given level of analgesia. Prolonged administration of Lorcet® 10/650 may produce constipation.
Genitourinary System: Ureteral spasm, spasm of vesical sphincters and urinary retention have been reported.
Respiratory Depression: Hydrocodone bitartrate may produce dose-related respiratory depression by acting directly on the brain stem respiratory center. Hydrocodone also affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing. If significant respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride. Apply other supportive measures when indicated.
DRUG ABUSE AND DEPENDENCE: Lorcet® 10/650 is subject to the Federal Controlled Substances Act (Schedule III). Psychic dependence, physical dependence, and tolerance may develop upon repeated administration of narcotics; therefore, Lorcet® 10/650 should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when Lorcet® 10/650 is used for a short time for the treatment of pain.
OVERDOSAGE: Acetaminophen: Signs and Symptoms: In acute acetaminophen overdose, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma, and thrombocytopenia may also occur. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.
Hydrocodone: Signs and Symptoms: Serious overdose with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdose, apnea, circulatory collapse, cardiac arrest and death may occur.
DOSAGE AND ADMINISTRATION: Dosage should be adjusted according to the severity of the pain and the response of the patient. However, it should be kept in mind that tolerance to hydrocodone can develop with continued use and that the incidence of untoward effects is dose related. The usual adult dosage is one tablet every four to six hours as needed for pain. The total 24 hour dose should not exceed 6 tablets.
CAUTION: Federal law prohibits dispensing without prescription. A Schedule CIII Controlled Substance. Manufactured by: MIKART, INC. ATLANTA, GA 30318 Manufactured for UAD Laboratories Division of Forest Pharmaceuticals, Inc. St. Louis, MO 63045 Rev. 6/94 Code 558A00

JAOA

federal update

From the CDC

Alcohol-related birth defects soar

Fetal alcohol syndrome (FAS) has increased sixfold during a 15-year period, according to figures from the Centers for Disease Control and Prevention (CDC). During 1979 to 1993, the number of such cases rose from 1 per 10,000 births to 6.7 per 10,000 births. A total of 2032 cases of FAS were reported per 9.4 million births during this period.

Whether the reported increase is due to greater diagnostic accuracy or an increase in the number of women who drink during their pregnancy remains uncertain.

One fifth of the women continued to imbibe even after they found out they were pregnant, according to the CDC.

From the FDA

Approval of medical devices to be accelerated

In a pilot program, medical devices deemed to pose a low or medium health risk will be tested by private medical groups rather than the US Food and Drug Administration (FDA). The change is intended to cut through the bureaucracy.

In testimony before an April hearing of the Senate Labor and Human Resources Committee, FDA Commissioner David A. Kessler, MD, made assurances that the safety of drugs and medical instruments will not be jeopardized. "We believe many medical devices simply don't pose a sufficient risk to be reviewed by the FDA prior to marketing," he maintained.

The 2-year pilot program will affect 10 additional categories of medical devices. The FDA already has exempted 125 categories from government approval before being marketed. These include syringes, oxygen masks, and certain surgical lasers.

Manufacturers of these devices will pay for the reviews by private medical groups. The pilot program is expected to begin in 1997.

In a related matter, the FDA will allow the exportation of drugs to other countries that have not yet been approved for marketing in the United States but *are* approved in the destination countries.

New class of asthma drug receives advisory approval

The Pulmonary and Allergy Drugs Advisory Committee to the FDA has recommended approval of Leutrol (zileuton) for the treatment of chronic asthma. Part of a new class of compounds called 5-lipoxygenase inhibitors, zileuton blocks the formation of leukotrienes.

In clinical trials involving more than 2500 patients, the drug was found to decrease the use of other concomitant medications, including inhaled beta-agonists and corticosteroids. Side effects included dyspepsia, abdominal pain, dizziness, and insomnia. ♦



FOREST PHARMACEUTICALS, INC.
UAD LABORATORIES
St. Louis, Missouri 63045