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, antianxiety 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 overdosage, 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 overdosage, 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.** Jackson, MS 39209 Rev. 11/92 Code 558A00

UAD LABORATORIES
Division of Forest Pharmaceuticals, Inc.
Jackson, Mississippi 39209-9658

FOREST PHARMACEUTICALS, INC.
Subsidiary of Forest Laboratories, Inc.
St. Louis, Missouri 63045

©1994 Forest Laboratories, Inc. L10-22A

From the FDA

Defective uncuffed pediatric endotracheal tubes threaten lives

A colorless material has been found inside some uncuffed pediatric endotracheal tubes. This material occludes the lumen, thereby preventing adequate ventilation of the patient. Because the material is not easily seen, the healthcare provider is not aware of the potential danger until *after* the patient has been intubated. Reintubation is then necessary, which in itself potentiates a life-threatening situation.

To prevent such emergencies, the agency recommends that healthcare providers take the following precautionary measures:

- Check the patency of all endotracheal tubes, including the tube and connector, *before* intubation.
- Do not allow solutions that can form film barriers to enter the lumen of the tube.
- Should the tube need to be reconnected to the connector, do not use lubricants that can form a barrier. In particular, avoid using cellulose products, such as lidocaine jelly as a lubricant. Lidocaine 2% has been shown to form a barrier when placed inside a 5-mm connector. After sufficient "curing time," this film forms a flexible obstruction that completely occludes the lumen of the endotracheal tube.

Obstructed endotracheal tubes *should be reported to the Food and Drug Administration. Do not discard these defective devices.* Defective devices should be reported to: Judy Kalson, FDA, Center for Devices and Radiological Health, Office of Science and Technology at (301) 443-2444.

Questions regarding this advisory should be directed to: Sherry Purvis-Wynn, RN, FDA, HFZ-510, 1390 Piccard Dr, Rockville, MD 20850; FAX (301) 594-2968.

Under the Safe Medical Devices Act of 1990, hospitals and other healthcare facilities are required to report deaths, serious illnesses, and injuries that are the result of the use of faulty medical devices. These reports should be addressed to: FDA, CDRH, MDR User Reporting, PO Box 3002, Rockville, MD 20847-3002; or telephone (301) 427-7500, FAX (301) 881-6670.

From the CDC

On-the-job deaths decline in 1980s

The number of Americans killed on the job between 1980 and 1989 declined 37%, down to 5.6 deaths per 100,000 workers in 1989, compared with 8.9 deaths per 100,000 workers in 1980. In 1980, a total of 7405 deaths took place at work. By 1989, that number dropped to 5714.

During the 10-year period, a total of 63,589 workers were killed. Motor vehicle accidents accounted for the most deaths—23.1%. Machine-related deaths came in second, responsible for 13.4% of on-the-job deaths. Homicides (12.1%), falls (9.5%), electrocutions (7.1%), struck by falling objects (6.5%), and other causes (28.3%) were responsible for the remainder of the deaths.

With the highest average annual death rate of 31.9 per 100,000 workers, the mining industry was found to be the most dangerous occupation. Construction came in second, with 25.6 deaths per 100,000 employees.

This report is the first one in which the Centers for Disease Control and Prevention analyzed data from all the states. ◆