Cetylev™ (acetylcysteine) effervescent tablets for oral solution

MANUFACTURED BY
Alpex Pharma SA
Switzerland

MARKETED AND DISTRIBUTED BY
Arbor Pharmaceuticals, LLC, Atlanta, GA 30328
Phone: 866-516-4950
www.arborpharma.com
www.cetylev.com

PRODUCT NAME
Cetylev™ (Effervescent Tablets)

ESTABLISHED NAME
(acetylcysteine)

NDC CODE
24338-700-10: 500-mg tablets
Carton of 20 (ten 2-count blister packs)
24338-725-10: 2.5-g tablets
Carton of 20 (ten 2-count blister packs)

MINIMUM ORDER QUANTITY
1 carton of 20, 500-mg tablets
(ten 2-count blister packs)
1 carton of 20, 2.5-g tablets
(ten 2-count blister packs)

HOW SUPPLIED
1 carton of 20, 500-mg tablets
(ten 2-count blister packs)
1 carton of 20, 2.5-g tablets
(ten 2-count blister packs)

DATED ITEMS
The expiration date is printed on each carton and blister pack.

PRESCRIPTION LEGEND
Prescription only

STORAGE REQUIREMENTS
Store between 20°C to 25°C (68°F to 77°F).
Excursions permitted to 15°C to 30°C (59°F to 86°F).
[See USP Controlled Room Temperature.]
Protect from moisture.
Store tablets in original blister package until use.

HOW TO ORDER
Ordering available through wholesalers. Please see reverse for details.

PRODUCT INFORMATION
For medical information:
Phone: 866-516-4950
E-mail: medinfo@arborpharma.com

To report an adverse event:
Arbor Pharmaceuticals
Phone: 866-516-4950
E-mail: aereports@arborpharma.com
FDA
Phone: 1-800-FDA-1088 (1-800-332-1088)
www.fda.gov/medwatch

DOSAGE
Each tablet contains 500 mg or 2.5 g of acetylcysteine.

Please see the full indication and Important Safety Information on the reverse side.
Indication

Cetylev is indicated to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen in patients with acute ingestion or from repeated supratherapeutic ingestion (RSI).

Important Safety Information

Hypersensitivity reactions, including generalized urticaria have been observed in patients receiving oral acetylcysteine for acetaminophen overdose. If hypersensitivity reactions occur, Cetylev should be discontinued unless it is deemed essential for patient management and the reactions can be otherwise controlled.

Risk of upper gastrointestinal hemorrhage may increase due to occasional severe and persistent vomiting as a symptom of acute acetaminophen overdose. Treatment with Cetylev may aggravate the vomiting and increase the risk of upper gastrointestinal hemorrhage in at risk patients (e.g., those with esophageal varices, peptic ulcers, etc.). Consider the risk/benefit for patients at risk of hemorrhage versus the risk of developing hepatic toxicity, and treat with Cetylev as needed.

Cetylev tablets contain sodium. Consider the total sodium content from dietary and non-dietary sources in patients who may be sensitive to excess sodium intake, such as those with congestive heart failure, hypertension, or renal impairment.

Acetaminophen and acetylcysteine cross the placenta. Delaying treatment in pregnant women with acetaminophen overdose and potentially toxic acetaminophen plasma levels may increase the risk of maternal and fetal morbidity and mortality.

There is no information regarding the presence of acetylcysteine in human milk, or the effects of acetylcysteine on the breastfed infant or on milk production. The development and health benefits of breastfeeding should be considered along with the mother’s clinical need for Cetylev and any potential adverse effects on the breastfed infant from Cetylev or from the underlying maternal condition.

Please refer to the Cetylev prescribing information for Recommended Dosage and Preparation and Administration Instructions in Adults and Pediatrics for Acute Acetaminophen Ingestion. For assistance with specific Cetylev dosage and administration information for acute ingestion or specific Cetylev dosage and administration information in patients with RSI, consider contacting your regional poison center at 1-800-222-1222, or alternatively, a special health professional assistance line for acetaminophen overdose at 1-800-525-6115.

Adverse Reactions

The most common adverse reactions were nausea, vomiting, other gastrointestinal symptoms, and rash with or without fever.