Indications and Usage

Acetylcysteine is indicated for the treatment of patients who are at risk for or who have developed:

- Congestive heart failure
- Pulmonary edema
- Acute respiratory distress syndrome
- Acute respiratory distress syndrome patients who are intubated or tracheostomy patients

Acetylcysteine should be used only for the indicated indications. The use of acetylcysteine for other indications is not recommended.

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Acetylcysteine should not be used to treat patients with bronchospasm due to asthma, since it will not relieve bronchospasm.

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Acetylcysteine As An Antidote For Acetaminophen Overdose

CLINICAL PHARMACOLOGY

(Antidote) Acetaminophen is rapidly absorbed from the upper gastrointestinal tract with peak plasma levels occurring between 30 and 60 minutes after oral administration. Over 40% of the oral dose is metabolized in the liver to form principally the sulfate and glucuronic acid conjugates which are also nontoxic and are rapidly excreted by the kidney. A small fraction of the oral dose is metabolized in the liver by the cytochrome P450 enzyme system to form a reactive, potentially toxic, intermediate metabolite which preferentially conjugates with hepatic glutathione to form an essentially inert metabolite. Acetylcysteine derivatives which are then excreted by the kidney. Therapeutic doses of acetylcysteine do not saturate the sulfuration and glucuronidation pathways and do not result in the formation of significant reactive metabolites. In the occasional instances where the patient is persistently unable to retain the orally administered acetylcysteine, the antidote may be administered by duodenal intubation.

Acetylcysteine has been shown to reduce the extent of liver injury following acetaminophen overdose. Its effectiveness depends on early oral administration, with benefit seen principally in patients treated within 16 hours of the overdose. Acetylcysteine probably protects the liver by maintaining or restoring the glutathione levels, or by acting as an alternate substrate for conjugation with, and thus deactivating, the reactive intermediate metabolite.

INDICATIONS AND USAGE

Acetylcysteine is not ordinarily, is indicated as an antidote to prevent or lessen hepatic injury which may occur following the ingestion of a potentially hepatotoxic quantity of acetaminophen.

It is essential to initiate treatment as soon as possible after the overdose and, in any case, within 24 hours of ingestion.

The following nomogram has been developed to estimate the probability that plasma levels in relation to intervals post ingestion will result in hepatitis.

Dose in relation to body weight are:

<table>
<thead>
<tr>
<th>Body Weight</th>
<th>Acetylcysteine mg kg</th>
<th>Acetylcysteine Diluent % Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 -19</td>
<td>140</td>
<td>5%</td>
</tr>
<tr>
<td>20 - 60</td>
<td>140</td>
<td>5%</td>
</tr>
<tr>
<td>61 - 100</td>
<td>140</td>
<td>5%</td>
</tr>
<tr>
<td>101 - 150</td>
<td>140</td>
<td>5%</td>
</tr>
<tr>
<td>151 - 200</td>
<td>140</td>
<td>5%</td>
</tr>
</tbody>
</table>

Loading Dose of Acetylcysteine **

<table>
<thead>
<tr>
<th>Acetylcysteine</th>
<th>ml of Diluent</th>
<th>ml of Total</th>
<th>ml of 5% Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>140</td>
<td>20</td>
<td>160</td>
<td>32</td>
</tr>
<tr>
<td>280</td>
<td>40</td>
<td>320</td>
<td>64</td>
</tr>
<tr>
<td>420</td>
<td>60</td>
<td>480</td>
<td>96</td>
</tr>
<tr>
<td>560</td>
<td>80</td>
<td>640</td>
<td>128</td>
</tr>
<tr>
<td>700</td>
<td>100</td>
<td>700</td>
<td>140</td>
</tr>
</tbody>
</table>

Supportive Treatment of Acetaminophen Overdose

Acetylcysteine is available in oral, inhalation, and parenteral forms.

Acetylcysteine solution, USP, is available as:

- **Acetylcysteine solution**, USP, contains acetylcysteine as the active ingredient and is sterile, nonpyrogenic, and has been shown to be compatible with Sodium Chloride for Injection, Sodium Chloride for Inhalation, Sterile Water for Injection, or Sterile Water for Inhalation.

- **Acetylcysteine solution** is not for parenteral injection.

Acetylcysteine is available in rubber stoppered glass vials containing 4, 10, or 30 mL. The 20% solution may be diluted to a lesser concentration with either Sodium Chloride for Injection, Sodium Chloride for Inhalation, Sterile Water for Injection, or Sterile Water for Inhalation.

Acetylcysteine solution is not for parenteral injection. It is available as:

- **Acetylcysteine solution** is sterile and can be used for inhalation (muscular agent) or oral administration (acetaminophen antidote).

- **Acetylcysteine solution** is not for parenteral injection. It is available as:

- **Acetylcysteine solution** contains 20 mg acetaminophen per mL. Sterile, not for injection.

- **Acetylcysteine solution** contains 20 mg acetaminophen per mL. Sterile, not for injection.

- **Acetylcysteine solution** contains 30 mg acetaminophen per mL. Sterile, not for injection.

- **Acetylcysteine solution** contains 30 mg acetaminophen per mL. Sterile, not for injection.

- **Acetylcysteine solution** contains 50 mg acetaminophen per mL. Sterile, not for injection.

- **Acetylcysteine solution** contains 50 mg acetaminophen per mL. Sterile, not for injection.

**References**


4. Mg IV 111NSO