For patients whose values are below the "possible" toxicity line (dotted line in nomogram):

- If the patient presents less than 8 hours after ingestion:
  - Obtain an acetaminophen concentration to determine whether or not to initiate treatment with CETYLEV immediately.
  - Administer a loading dose of CETYLEV immediately.

- If the patient presents more than 8 hours after ingestion:
  - Obtain acetaminophen concentration to determine whether or not to initiate treatment with CETYLEV immediately.
  - Administer a loading dose of CETYLEV immediately.

- If the acetaminophen concentration cannot be obtained:
  - Administer a loading dose of CETYLEV immediately.

- If the patient presents more than 8 hours after ingestion and the acetaminophen concentration is in the non-toxic range:
  - Monitor hepatic and renal function and electrolytes, and also the clinical presentation of the patient.
  - Continue treatment with the maintenance dose for a total of 17 doses.

- If the patient presents more than 8 hours after ingestion and the acetaminophen concentration was in the potentially hepatotoxic range:
  - Monitor hepatic and renal function and electrolytes, and also the clinical presentation of the patient.
  - Continue treatment with the maintenance dose for a total of 17 doses.

If the patient presents less than 8 hours after ingestion and the acetaminophen concentration was in the non-toxic range:

- Monitor hepatic and renal function and electrolytes, and also the clinical presentation of the patient.
- Continue treatment with the maintenance dose for a total of 17 doses.

If the patient presents more than 8 hours after ingestion and the acetaminophen concentration was in the potentially hepatotoxic range:

- Monitor hepatic and renal function and electrolytes, and also the clinical presentation of the patient.
- Continue treatment with the maintenance dose for a total of 17 doses.

If the patient presents less than 8 hours after ingestion and the acetaminophen concentration was in the potentially hepatotoxic range:

- Monitor hepatic and renal function and electrolytes, and also the clinical presentation of the patient.
- Continue treatment with the maintenance dose for a total of 17 doses.
of breastfeeding should be considered along with the mother's infant or on milk production. The development and health benefits in human milk, or the effects of acetylcysteine on the breastfed infant.

5.2 Risk of Upper Gastrointestinal Hemorrhage

Acetylcysteine may aggravate the vomiting and increase the risk of upper gastrointestinal (GI) hemorrhage, particularly in patients with peptic ulcer disease. In patients with peptic ulcer disease, the risk of upper gastrointestinal hemorrhage may be reduced with the addition of cimetidine, 300 mg orally twice a day, for 10 days.

5.3 Acute Kidney Injury

In patients with acute kidney injury, the administration of 1000 mg/kg/day of acetylcysteine (0.3 times the recommended human dose based on body surface area) caused a profound increase in serum creatinine. In this animal study, the increased serum creatinine was transient. There were no data available to support the safety of acetylcysteine in patients with acute kidney injury.

[Table 1: CETYLEV Loading Dose]

<table>
<thead>
<tr>
<th>Body weight</th>
<th>Actual dose (grams)</th>
<th>Dose to be administered using an oral syringe</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 to 19</td>
<td>1.0 gram</td>
<td>Dissolve two 2.5 gram CETYLEV effervescent tablets in 100 mL of water. The result is the dose in mL for dilution.</td>
</tr>
<tr>
<td>20 to 29</td>
<td>1.5 gram</td>
<td>Dissolve two 2.5 gram CETYLEV effervescent tablets in 150 mL of water.</td>
</tr>
<tr>
<td>30 to 39</td>
<td>2.0 gram</td>
<td>Dissolve two 2.5 gram CETYLEV effervescent tablets in 200 mL of water.</td>
</tr>
<tr>
<td>40 to 49</td>
<td>2.5 gram</td>
<td>Dissolve two 2.5 gram CETYLEV effervescent tablets in 250 mL of water.</td>
</tr>
<tr>
<td>50 to 59</td>
<td>3.0 gram</td>
<td>Dissolve two 2.5 gram CETYLEV effervescent tablets in 300 mL of water.</td>
</tr>
</tbody>
</table>

[Table 2: CETYLEV Maintenance Dose]

<table>
<thead>
<tr>
<th>Body weight</th>
<th>Actual dose (grams)</th>
<th>Dose to be administered using an oral syringe</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 to 19</td>
<td>0.5 gram</td>
<td>Dissolve one 2.5 gram CETYLEV effervescent tablet in 50 mL of water.</td>
</tr>
<tr>
<td>20 to 29</td>
<td>0.75 gram</td>
<td>Dissolve one 2.5 gram CETYLEV effervescent tablet in 75 mL of water.</td>
</tr>
<tr>
<td>30 to 39</td>
<td>1.0 gram</td>
<td>Dissolve one 2.5 gram CETYLEV effervescent tablet in 100 mL of water.</td>
</tr>
<tr>
<td>40 to 49</td>
<td>1.25 gram</td>
<td>Dissolve one 2.5 gram CETYLEV effervescent tablet in 125 mL of water.</td>
</tr>
<tr>
<td>50 to 59</td>
<td>1.5 gram</td>
<td>Dissolve one 2.5 gram CETYLEV effervescent tablet in 150 mL of water.</td>
</tr>
</tbody>
</table>

[Table 3: ADEQUATION OF NURSING AND FEEDING]

1. Adequacy of Nursing

In animal studies, administration of acetylcysteine to dams during pregnancy and lactation, or during the mating period, resulted in no adverse clinical effects on the nursing or weaned offspring. In animal studies, administration of 1000 mg/kg/day of acetylcysteine during pregnancy, or during the mating period, resulted in no adverse clinical effects on the nursing or weaned offspring. In animal studies, administration of 1000 mg/kg/day of acetylcysteine during pregnancy, or during the mating period, resulted in no adverse clinical effects on the nursing or weaned offspring.

2. Adequacy of Feeding

In animal studies, administration of acetylcysteine to dams during pregnancy and lactation, or during the mating period, resulted in no adverse clinical effects on the nursing or weaned offspring. In animal studies, administration of 1000 mg/kg/day of acetylcysteine during pregnancy, or during the mating period, resulted in no adverse clinical effects on the nursing or weaned offspring. In animal studies, administration of 1000 mg/kg/day of acetylcysteine during pregnancy, or during the mating period, resulted in no adverse clinical effects on the nursing or weaned offspring.