Acetylcysteine is used by intravenous infusion preferably using Glucrose 5% or the infusion fluid Sodium Chloride 0.9% solution may be used if Glucose 5% is not suitable.

The full course of treatment with acetylcysteine comprises 3 consecutive intravenous infusions. Doses should be administered sequentially with no break between the infusions. The patient should receive a total dose of 300 mg/kg body weight over a 21 hour period. Continued treatment with acetylcysteine (given at the dose and rate as set out in the third infusion) may be necessary depending on the clinical evaluation of the individual patient.

**Adults**
- Weight the patient to determine the correct weight band.
- Use the adult dosage table to determine the appropriate volume of acetylcysteine (ampoule volume) to be added to the infusion fluid for each of the 3 infusion periods.

**First infusion**
Add the appropriate volume of acetylcysteine injection to 200 ml of infusion fluid and infuse over 1 hour.

**Second infusion**
Add the appropriate volume of acetylcysteine injection to 500 ml of infusion fluid and infuse over the next 4 hours.

**Third infusion**
Add the appropriate volume of acetylcysteine injection to 1 L of infusion fluid and infuse over the next 16 hours.

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**Paediatric Dosage Table**

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Volume (ml)</th>
<th>Rate (ml/hr)</th>
<th>Duration (hr)</th>
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</thead>
<tbody>
<tr>
<td>5-10</td>
<td>15-20</td>
<td>60-120</td>
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<td>31-35</td>
<td>80-120</td>
<td>600-1200</td>
<td>48</td>
</tr>
<tr>
<td>36-40</td>
<td>120-160</td>
<td>1200-1600</td>
<td>72</td>
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</tbody>
</table>

Dose calculations are based on weight in the middle of each band. If the patient weighs less than 40kg use the paediatric dosage table. Ampoule volume has been rounded up to the nearest whole number.

The Summary of Product Characteristics should be referred to for full prescribing information.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or nurse immediately if you notice any of the following side effects:
- swelling of the face, lips or tongue
- wheezing, difficulty in breathing
- feeling faint
- irritation at the injection site
- itching, rash, hives
- flushing (red face or feeling hot)
- low blood pressure
- rapid heart beat or increased blood pressure
- vomiting, thirst or restlessness
- sweating, feeling unwell
- raised temperature, hot, red face and skin
- decreased or indisposed appetite (anorexia)
- reduced urine output
- blood clots, coughing
- blood in your urine
- blurred vision
- impotence or reduced sex drive (impotence or reduced sex drive)
- unusual tiredness or weakness
- problems with your kidneys
- skin rash (rash)
- dry skin and hair
- feeling very tired or weakness
- loss of appetite
- nausea or vomiting
- blood in your urine
- backache
- persistent headache
- joint pain
- breathlessness
- increased liver function tests
- chest pain
- sweats
- nosebleeds
- shock
- a little blood in your urine
- aches and pains
- bleeding gums
- blood in your urine
- backache
- breathlessness
- a rash
- persistent cough
- aches and pains
- breathing difficulties
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**5. How to store Acetylcysteine Injection**

Keep this medicine out of the sight and reach of children. Do not use Acetylcysteine Injection after the expiry date which is stated on the label. The expiry date refers to the last day of that month. The doctor or nurse will check that the product has not passed this date.

Once diluted according to directions, start using within 3 days.

Do not store above 25°C. Store ampoules in the original container until use.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

What Acetylcysteine Injection contains

The active ingredient is Acetylcysteine 200mg/ml.

The other ingredients are disodium edetate, sodium hydroxide and water for injection.

What Acetylcysteine Injection looks like and contents of the pack:

Acetylcysteine Injection is a clear colourless solution for infusion.

The product is available in (Type I) clear glass ampoules in pack sizes of 10 x 10ml, 10 x 20ml or 5 x 20ml ampoules.

What Acetylcysteine Injection contains

The active ingredient is Acetylcysteine 200 mg/1 ml.

The other ingredients are disodium edetate, nitrogen gas, sodium hydroxide and water for injection.

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Marketing Authorisation holder:
Aurum Pharmaceuticals Ltd., T/A Martindale Pharma, 63-67 Barnet Road, Bampton Road, D-22946 Trittau, Germany.

Marketing Authorisation Number: PL 12064/0026

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