

Acetylcysteine 200mg/ml Injection

Summary of Product Characteristics Updated 30-Apr-2018 | Martindale Pharma, an Ethypharm Group Company

1. Name of the medicinal product

Acetylcysteine 200 mg/ml Injection

2. Qualitative and quantitative composition

Acetylcysteine 200mg per ml (as N-acetylcysteine)

Each 10ml ampoule contains 2g N-acetylcysteine

Each 20ml ampoule contains 4g N-acetylcysteine

Excipients with known effect:

Each 10ml of N-acetylcysteine for Infusion contains 322.6 mg sodium.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Clear colourless solution for Infusion

4. Clinical particulars

4.1 Therapeutic indications

N-acetylcysteine is indicated for the treatment of paracetamol overdose in patients:

- a) who have taken a staggered overdose irrespective of plasma paracetamol level. Staggered is defined as an overdose where the paracetamol was ingested over a period of 1 hour or more; or
- b) where there is any doubt over the time of the overdose, irrespective of plasma paracetamol level; or
- c) who present with a plasma paracetamol level on or above a line joining points of 100mg/L at 4h and 15mg/L at 15h (see below nomogram).

4.2 Posology and method of administration

The injection should be administered by intravenous infusion preferably using Glucose 5% as the infusion fluid. Sodium Chloride 0.9% solution may be used if Glucose 5% is not suitable.

Adults

The full course of treatment with acetylcysteine comprises 3 consecutive intravenous infusions:

First infusion

Initial loading dose of 150 mg/kg body weight infused in 200 mL over 1 hour.

Second infusion

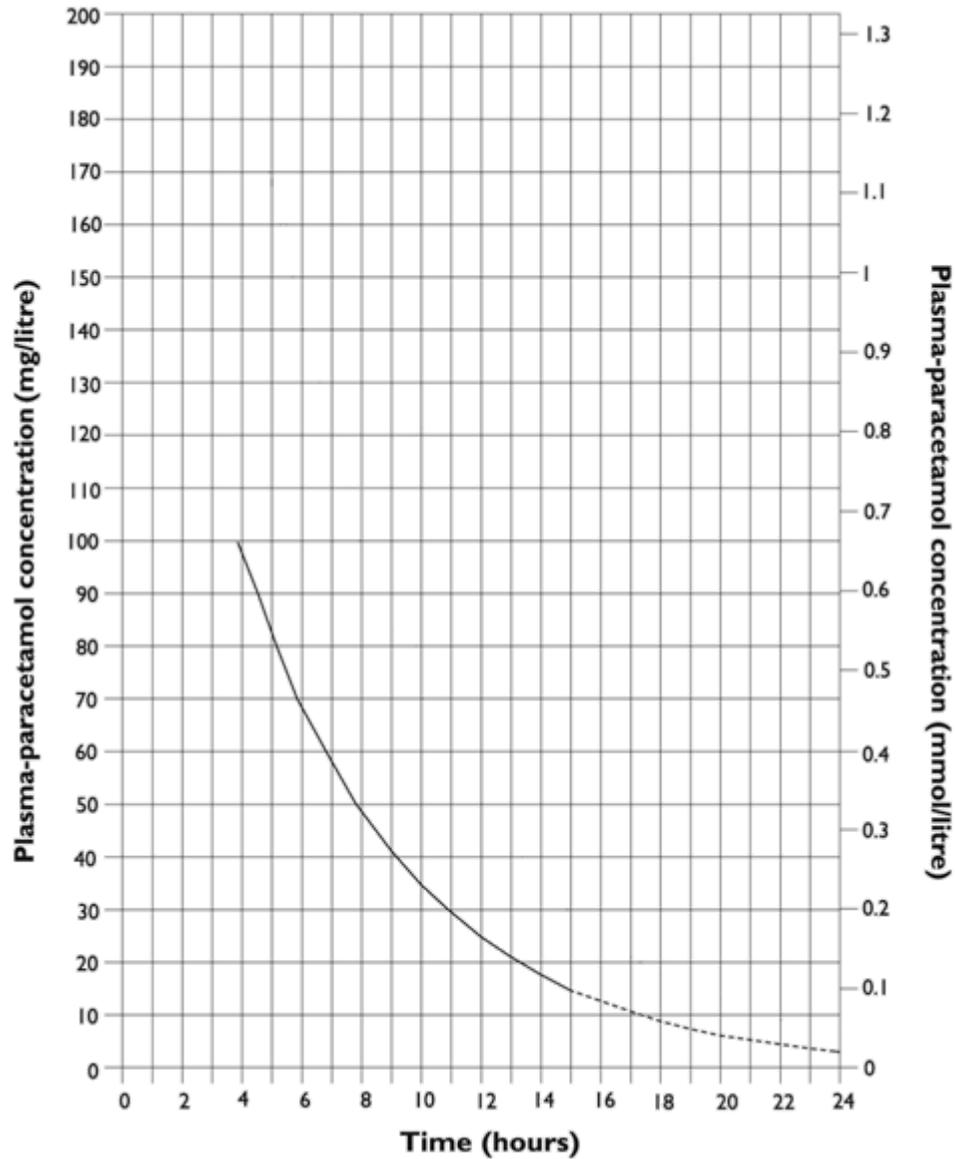
50 mg/kg in 500 mL over the next 4 hours.

Third infusion

100 mg/kg in 1 litre over the next 16 hours.

The patient should therefore receive a total of 300 mg/kg over a 21 hour period.

Continued treatment with acetylcysteine (given at the dose and rate as used in the third infusion) may be necessary depending on the clinical evaluation of the individual patient.



A ceiling weight of 110 kg should be used when calculating the dosage for obese patients.

Dosage should be calculated using the patient's actual weight.