




| | | EMLc | ATC codes: V03AB23 |
|--------------------------|--|------------------|--------------------|
| Indication | Exposure to or harmful effects of undetermined intent of analgesics, antipyretics or nonsteroidal anti-inflammatory drugs | ICD11 code: PH44 | |
| INN | Acetylcysteine | | |
| Medicine type | Chemical agent | | |
| List type | Core (EML) (EMLc) | | |
| Formulations | Parenteral > General injections > IV: 200 mg per mL in 10 mL ampoule Oral > Liquid: 10% (EMLc) ; 20% (EMLc) | | |
| EML status history | First added in 1999 (TRS 895) Changed in 2007 (TRS 950) Changed in 2009 (TRS 958) | | |
| Sex | All | | |
| Age | Also recommended for children | | |
| Therapeutic alternatives | The recommendation is for this specific medicine | | |
| Patent information | Patents have expired in most jurisdictions Read more about patents .  | | |
| Wikipedia | Acetylcysteine  | | |
| DrugBank | Acetylcysteine  | | |

Summary of evidence and Expert Committee recommendations

In 2009, the EMLc Subcommittee considered the review commissioned by the Secretariat of acetylcysteine as an antidote for paracetamol toxicity in children. The review summarized the clinical evidence for use of acetylcysteine in adults and noted that no randomized efficacy trials have been conducted in children. There is significant clinical evidence in adult populations to suggest that oral and intravenous acetylcysteine are equally effective. The intravenous form of acetylcysteine can also be administered orally. A small study involving 25 paediatric patients demonstrated comparable efficacy between intravenous and oral acetylcysteine. Several observational studies involving the use of oral acetylcysteine showed a decrease in the incidence of hepatotoxicity in those patients in whom therapy was initiated within 10 hours of ingestion. However these studies involved only small numbers of paediatric patients. The Subcommittee noted that the major concern with regard to adverse effects in children is that intravenous infusion in children may be associated with hyponatraemia if excessive fluids are administered in conjunction with acetylcysteine and that anaphylactoid reactions are associated with the parenteral formulation. The Subcommittee agreed that acetylcysteine is considered the treatment of choice for paracetamol toxicity where the dose and/or paracetamol plasma concentrations would suggest the risk of serious hepatotoxicity from an acute ingestion. It was agreed that intravenous acetylcysteine should remain on the list and oral formulations be added to the EMLc.

