Acetylcysteine has been used to treat meconium ileus in neonates and distal obstruction syndrome in children with **cystic fibrosis**, although the *BNFC* states that evidence of its efficacy is lacking. Such use is not licensed in the UK, but if it is to be used the *BNFC* suggests an oral dose of acetylcysteine 200 to 400 mg up to 3 times daily for meconium ileus in neonates. For the *treatment* of distal intestinal obstruction syndrome in children with cystic fibrosis, a single oral dose is recommended as follows:

1 month to 2 years: 400 mg to 3 g
2 to 7 years: 2 to 3 g
7 to 18 years: 4 to 6 g

Acetylcysteine is given by intravenous infusion or by mouth in the treatment of **paracetamol poisoning**. Doses for children are similar to adults although the volume of intravenous fluid is modified. The *BNFC* suggests the following *intravenous* doses:

neonates to 5 years (or body-weight under 20 kg): initially 150 mg/kg in 3 mL/kg glucose 5% given over 15 minutes, followed by 50 mg/kg in 7 mL/kg glucose 5% given over 4 hours, then 100 mg/kg in 14 mL/kg glucose 5% given over 16 hours

5 to 12 years (or body-weight over 20 kg): initially 150 mg/kg in 100 mL glucose 5% given over 15 minutes, followed by 50 mg/kg in 250 mL glucose 5% given over 4 hours, then 100 mg/kg in 500 mL glucose 5% given over 16 hours

12 to 18 years: adult dose In the USA, the following *oral* dose has also been suggested for children: 140 mg/kg initially, followed by 70 mg/kg every 4 hours for an additional 17 doses.

Adverse Effects

Hypersensitivity reactions have been reported in patients receiving acetylcysteine, including bronchospasm, angioedema, rashes and pruritus; hypotension, or occasionally hypertension, may occur. Other adverse effects reported with acetylcysteine include flushing, nausea and vomiting, fever, syncope, sweating, arthralgia, blurred vision, disturbances of liver function, acidosis, convulsions, and cardiac or respiratory arrest. Haemoptysis, rhinorrhoea, and stomatitis have been associated with inhalation of acetylcysteine

Precautions

Acetylcysteine should be used with caution in asthmatic patients. It should also be used with caution in patients with a history of peptic ulcer disease, both because drug-induced nausea and vomiting may increase the risk of gastrointestinal haemorrhage in patients predisposed to the condition, and because of a theoretical risk that mucolytics may disrupt the gastric mucosal barrier.

Asthma. Bronchospasm precipitated in 2 asthmatic patients and severe asthma and respiratory arrest in another have been reported after intravenous treatment with acetylcysteine. There is also a report of a patient with brittle asthma who had a similar reaction and subsequently died after receiving intravenous treatment with acetylcysteine. The increased risk does not justify delaying or witholding acetylcysteine in asthmatic patients with paracetamol poisoning, but consideration might be given to initial intravenous infusion over 30 to 60 minutes rather than the conventional 15 minutes. However, a large multicentre study found no benefit from the more prolonged infusion—see Paracetamol
under Poisoning and Toxicity, below.

WARNINGS

Generalized urticaria has been observed rarely in patients receiving oral acetylcysteine for acetaminophen overdose. If this occurs or other allergic symptoms appear, treatment with acetylcysteine should be discontinued unless it is deemed essential and the allergic symptoms can be otherwise controlled. If encephalopathy due to hepatic failure becomes evident, acetylcysteine treatment should be discontinued to avoid further administration of nitrogenous substances. There are no data indicating that acetylcysteine influences hepatic failure, but this remains a theoretical possibility.

PREGNANT WOMEN

In four pregnant women with acetaminophen toxicity, oral or I.V. acetylcysteine was administered at the time of delivery. Acetylcysteine crossed the placenta and was measurable in newborn circulation and cord blood of three viable infants following delivery and in cardiac blood of a fourth infant at autopsy (22 weeks gestational age who died 3 hours after birth). No adverse sequelae developed in the three viable infants. All mothers recovered and none of the infants had evidence of acetaminophen poisoning.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when acetylcysteine is administered to a nursing woman.

Storage: - Store at controlled room temperature 20°C to 25°C. Protected from light. Improper Storage may deteriorate the product

Medicine: - Keep out of reach of children.

Presentation: - Each pack contain 2 ml glass ampoule containing 400 mg of Acetylcystine.

Manufactured by:
AMERICAN REMEDIES
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
© ICO: American Remedies LLC, DE, USA
Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A, Harihar Complex, Bhiwandi, Mumbai - 421302
At: Vill. Surajpur Nahan Road Paonta Sahib, Distt. Sirmour, Himachal Pradesh-173001
E-mail: info@americanremedies.in
© Copyright

WHO GMP CERTIFIED

Scan for Batch Certificate

For the use only of a Registered Medical Practitioner or a hospital or a laboratory

℞ Acetylcysteine Solution USP

AMERICAN MUCANIX 400 Injection

FOR IV USE ONLY

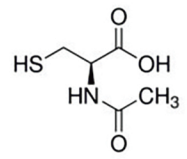
Composition:-

Each ml Contains:-

Acetylcysteine	USP	200 mg.
Water for Injection	IP	q.s

Description: -

Acetylcysteine injection is an intravenous (I.V.) medication for the treatment of acetaminophen overdose. Acetylcysteine is the nonproprietary name for the N-acetyl derivative of the naturally occurring amino acid, L-cysteine (N-acetyl-L-cysteine, NAC). The compound is a white crystalline powder, which melts in the range of 104° to 110°C and has a very slight odor. The molecular formula of the compound is $C_5H_9NO_3S$, and its molecular weight is 163.2. Acetylcysteine has the following structural formula:



Acetylcysteine

Acetylcystine Injection is supplied as a sterile solution in Ampoules containing 20% w/v (200 mg/mL) acetylcysteine. The pH of the solution ranges from 6.0 to 7.5. With Sterile Water for Injection IP.

PHARMACOLOGY

Pharmacokinetics

Acetylcysteine is rapidly absorbed from the gastrointestinal tract and peak plasma concentrations occur about 0.5 to 1 hour after oral doses of 200 to 600 mg. Some studies indicate dosedependent pharmacokinetics with peak concentrations, the time taken to reach peak concentrations, and bioavailability increasing with increasing doses. Acetylcysteine may be present in plasma as the parent compound or as various oxidised metabolites such as *N*-acetylcystine, *N,N*-diacetylcystine, and cysteine either free or bound to plasma proteins by labile disulfide bonds or as a fraction incorporated into protein peptide chains. In a study about 50% was in a covalently protein-bound form 4 hours after a dose. Oral bioavailability is low and mean values have ranged from 4 to 10% depending on whether total acetylcysteine or just the reduced forms are measured. It has been suggested that acetylcysteine's low oral bioavailability may be due to metabolism in the gut wall and first-pass metabolism in the liver. Renal clearance may account for about 30% of total body clearance. On intravenous dosage mean terminal half-lives have been calculated to be 1.95 and 5.58 hours for reduced and total acetylcysteine, respectively; the terminal half-life of total acetylcysteine was 6.25 hours after oral doses

Dosage and Administration

Acetylcysteine is a mucolytic that reduces the viscosity of secretions probably by the splitting of disulphide bonds in mucoproteins. This action is greatest at a pH of 7 to 9 and the pH may have been adjusted in commercial preparations with sodium hydroxide. It is sometimes stated that acetylcysteine sodium is used, although the dose is expressed in terms of acetylcysteine. Acetylcysteine is also able to promote the detoxification of an intermediate paracetamol metabolite, and has a key role in the management of paracetamol overdosage.

Acetylcysteine is used for its **mucolytic** activity in respiratory disorders associated with productive cough. It can be given by nebulisation of 3 to 5 mL of a 20% solution or 6 to 10 mL of a 10% solution through a face mask or mouthpiece 3 or 4 times daily. If necessary 1 to 10 mL of a 20% solution or 2 to 20 mL of a 10% solution may be given by nebulisation every 2 to 6 hours. It can also be given by direct endotracheal instillation of 1 to 2 mL of a 10 to 20% solution as often as every hour. Mechanical suction of the liquefied secretions may be necessary, and nebulisers containing iron, copper, or rubber components should not be used.

· **If given intravenously**: 150 mg/kg of acetylcysteine in 200 mL of glucose 5% is given initially over 15 minutes, followed by infusion of 50 mg/kg in 500 mL of glucose 5% over the next 4 hours and then 100 mg/kg in one litre of glucose 5% over the next 16 hours. Sodium chloride 0.9% may be used where glucose 5% is unsuitable.

Acetylcysteine is reported to be most effective when given within 8 hours of paracetamol overdosage, with the protective effect diminishing after this time. However, starting treatment with acetylcysteine later (up to and beyond 24 hours) may still be of benefit (see also below).

Administration in children.

Acetylcysteine is used for its **mucolytic** activity in respiratory disorders associated with productive cough. Doses in children are similar to adults; 3 to 5 mL of a 20% solution, or 6 to 10 mL of a 10% solution, may be nebulised through a face mask or mouthpiece 3 or 4 times daily. If necessary 1 to 10 mL of a 20% solution, or 2 to 20 mL of a 10% solution, may be given by nebulisation every 2 to 6 hours. It can also be given by direct endotracheal instillation of 1 to 2 mL of a 10 to 20% solution as often as every hour.

Acetylcysteine has also been given orally in a variety of dosage forms. Licensed doses and age ranges vary somewhat from country to country and even from preparation to preparation. For example, in France, children may be given the following doses:

1 month to 2 years: 100 mg twice daily
2 to 7 years: 200 mg twice daily
7 years and over: 200 mg 3 times daily (adult dose)

In Germany and Switzerland, however, a more typical dose for children under 2 years of age is 50 mg two or three times daily.