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Acetylcysteine

Acetylcysteine, also known as **N-acetylcysteine** (**NAC**), is a medication that is used to treat paracetamol overdose and to loosen thick mucus in individuals with chronic bronchopulmonary disorders like pneumonia and bronchitis.^[2] It has been used to treat lactobezoar in infants. It can be taken intravenously, by mouth, or inhaled as a mist.^[2] Some people use it as a dietary supplement.^{[6][7]}

Common side effects include nausea and vomiting when taken by mouth.^[2] The skin may occasionally become red and itchy with any route of administration.^[2] A non-immune type of anaphylaxis may also occur.^[2] It appears to be safe in pregnancy.^[2] For paracetamol overdose, it works by increasing the level of glutathione, an antioxidant that can neutralise the toxic breakdown products of paracetamol.^[2] When inhaled, it acts as a mucolytic by decreasing the thickness of mucus.^[8]

Acetylcysteine was initially patented in 1960 and came into medical use in 1968.^{[9][10][11]} It is on the World Health Organization's List of Essential Medicines.^[12] It is available as a generic medication and is inexpensive.^[13]

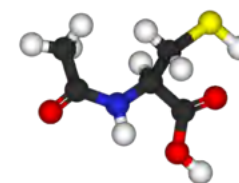
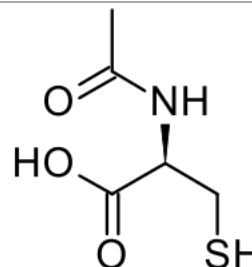
The sulfur-containing amino acids cysteine and methionine are more easily oxidized than the other amino acids.^{[14][15]}

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Acetylcysteine



Clinical data

Pronunciation	/əˈsiːtəlˈsɪstiːn/ and similar (/əˈsɛtəl- , /æsitəl- , -tiːn /)
Trade names	Acetadote, Fluimucil, Mucomyst, others
Other names	N-acetylcysteine; N-acetyl-L-cysteine; NALC; NAC
AHFS/Drugs.com	Monograph (https://www.drugs.com/monograph/acetylcysteine.html)
License data	 US DailyMed : Acetylcysteine (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Acetylcysteine) US FDA : Acetylcysteine (https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchTerm=Acetylcysteine&SearchType=BasicSearch)
Pregnancy category	 AU : B2
Routes of administration	By mouth, injection,

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Uses

Paracetamol overdose

Intravenous and oral formulations of acetylcysteine are available for the treatment of paracetamol (acetaminophen) overdose.^[16] When paracetamol is taken in large quantities, a minor metabolite called *N*-acetyl-*p*-benzoquinone imine (NAPQI) accumulates within the body. It is normally conjugated by glutathione, but when taken in excess, the body's glutathione reserves are not sufficient to deactivate the toxic NAPQI. This metabolite is then free to react with key hepatic enzymes, thereby damaging liver cells. This may lead to severe liver damage and even death by acute liver failure.

In the treatment of paracetamol (acetaminophen) overdose, acetylcysteine acts to maintain or replenish depleted glutathione reserves in the liver and enhance non-toxic metabolism of acetaminophen.^[17] These actions serve to protect liver cells from NAPQI toxicity. It is most effective in preventing or lessening hepatic injury when administered within 8–10 hours after overdose.^[17] Research suggests that the rate of liver toxicity is approximately 3% when acetylcysteine is administered within 10 hours of overdose.^[16]

Although IV and oral acetylcysteine are equally effective for this indication, oral administration is generally poorly tolerated due to the higher dosing required to overcome its low oral bioavailability,^[18] its foul taste and odour, and a higher incidence of adverse

	inhalation
<u>ATC code</u>	<u>R05CB01</u> (WHO (https://www.whooc.no/atc_ddd_index/?code=R05CB01)) <u>S01XA08</u> (WHO (https://www.whooc.no/atc_ddd_index/?code=S01XA08)) <u>V03AB23</u> (WHO (https://www.whooc.no/atc_ddd_index/?code=V03AB23))
	Legal status
<u>Legal status</u>	<u>AU</u> : S2 (Pharmacy medicine) <u>BR</u> : OTC (Over the counter) (by mouth, IV, inhalation) <u>US</u> : OTC (by mouth), Rx-only (IV, inhalation)
	Pharmacokinetic data
<u>Bioavailability</u>	10% (Oral) ^[1]
<u>Protein binding</u>	50 to 83% ^[2]
<u>Metabolism</u>	Liver ^[2]
<u>Elimination half-life</u>	5.6 hours ^[3]
<u>Excretion</u>	Renal (30%), ^[2] faecal (3%)
	Identifiers
<u>IUPAC name</u>	(2 <i>R</i>)-2-acetamido-3-sulfanylpropanoic acid ^[4]
<u>CAS Number</u>	616-91-1 (https://commonchemistry.cas.org/detail?cas_rn=616-91-1) ✓
<u>PubChem CID</u>	12035 (https://pubchem.ncbi.nlm.nih.gov/compound/12035)
<u>DrugBank</u>	DB06151 (https://www.drugbank.ca/drugs/DB06151) ✓
<u>ChemSpider</u>	11540 (https://www.chemspider.com/Chemical-Structure.11540.html) ✓
<u>UNII</u>	WYQ7N0BPYC (https://precision.fda.gov/uniisearch/srs/unii/WYQ7N0BPYC)

effects when taken by mouth, particularly nausea and vomiting. Prior pharmacokinetic studies of acetylcysteine did not consider acetylation as a reason for the low bioavailability of acetylcysteine.^[19] Oral acetylcysteine is identical in bioavailability to cysteine precursors.^[19] However, 3% to 6% of people given intravenous acetylcysteine show a severe, anaphylaxis-like allergic reaction, which may include extreme breathing difficulty (due to bronchospasm), a decrease in blood pressure, rash, angioedema, and sometimes also nausea and vomiting.^[20] Repeated doses of intravenous acetylcysteine will cause these allergic reactions to progressively worsen in these people.

Several studies have found this anaphylaxis-like reaction to occur more often in people given intravenous acetylcysteine despite serum levels of paracetamol not high enough to be considered toxic.^{[21][22][23][24]}

Lungs

Inhaled acetylcysteine has been used for mucolytic ("mucus-dissolving") therapy in addition to other therapies in respiratory conditions with excessive and/or thick mucus production. It is also used post-operatively, as a diagnostic aid, and in tracheotomy care. It may be considered ineffective in cystic fibrosis.^[25] A 2013 Cochrane review in cystic fibrosis found no evidence of benefit.^[26]

Acetylcysteine is used in the treatment of obstructive lung disease as an adjuvant treatment.^{[27][28][29]}

Kidney and bladder

Evidence for the benefit of acetylcysteine to prevent radiocontrast induced kidney disease is mixed.^[30]

Acetylcysteine has been used for cyclophosphamide-induced haemorrhagic cystitis, although mesna is generally preferred due to the ability of acetylcysteine to diminish the effectiveness of cyclophosphamide.^[31]

Psychiatry

Acetylcysteine has been studied for major psychiatric disorders,^{[32][33][34][35]} including bipolar disorder,^[32] major depressive disorder, and schizophrenia.^{[33][34]}

KEGG	D00221 (https://www.kegg.jp/entry/D00221) ✓
ChEBI	CHEBI:28939 (https://www.ebi.ac.uk/chebi/searchId.do?chebId=CHEBI:28939) ✓
ChEMBL	ChEMBL600 (https://www.ebi.ac.uk/chembl/db/index.php/compound/inspect/ChEMBL600) ✓
CompTox Dashboard (EPA)	DTXSID5020021 (https://comptox.epa.gov/dashboard/chemical/details/DTXSID5020021)
ECHA InfoCard	100.009.545 (https://echa.europa.eu/substance-information/-/substanceinfo/100.009.545)
Chemical and physical data	
Formula	C ₅ H ₉ NO ₃ S
Molar mass	163.19 g·mol ^{−1}
3D model (JSmol)	Interactive image (https://chemapps.stolaf.edu/jmol/jmol.php?model=C%2FC%28%3DN%2F%5BC%40%40H%5D%28CS%29C%28%3DO%29O%29%2FO)
Specific rotation	+5° (c = 3% in water) ^[5]
Melting point	109 to 110 °C (228 to 230 °F) ^[5]
SMILES	C/C(=N/[C@@H](CS)C(=O)O)/O
InChI	InChI=1S/C5H9NO3S/c1-3(7)6-4(2-10)5(8)9/h4,10H,2H2,1H3,(H,6,7)(H,8,9)/t4-/m0/s1 ✓ Key:PWKSKIMOESPYIA-BYPYZUCNSA-N ✓
	(verify)

Tentative evidence exists for *N*-acetylcysteine also in the treatment of Alzheimer's disease, autism, obsessive-compulsive disorder, specific drug addictions (cocaine), drug-induced neuropathy, trichotillomania, excoriation disorder, and a certain form of epilepsy (progressive myoclonic).^{[33][34][36]} Preliminary evidence showed efficacy in anxiety disorder, attention deficit hyperactivity disorder and mild traumatic brain injury although confirmatory studies are required.^{[36][37][38][39]} Tentative evidence also supports use in cannabis use disorder.^[40]

Bipolar disorder

In bipolar disorder, *N*-acetylcysteine has been repurposed as an augmentation strategy for depressive episodes in light of the possible role of inflammation in the pathogenesis of mood disorders. Nonetheless, meta-analytic evidence shows that add-on *N*-acetylcysteine was more effective than placebo only in reducing depression scales scores (low quality evidence), without positive effects on response and remission outcomes, limiting its possible role in clinical practice to date.^[32]

Addiction

Evidence to date does not support the efficacy for *N*-acetylcysteine in treating addictions to gambling, methamphetamine, or nicotine.^[36] Based upon limited evidence, NAC appears to normalize glutamate neurotransmission in the nucleus accumbens and other brain structures, in part by upregulating the expression of excitatory amino acid transporter 2 (EAAT2), a.k.a. glutamate transporter 1 (GLT1), in individuals with addiction.^[41] While NAC has been demonstrated to modulate glutamate neurotransmission in adult humans who are addicted to cocaine, NAC does not appear to modulate glutamate neurotransmission in healthy adult humans.^[41] NAC has been hypothesized to exert beneficial effects through its modulation of glutamate and dopamine neurotransmission as well as its antioxidant properties.^[34]

Microbiological use

Acetylcysteine can be used in Petroff's method of liquefaction and decontamination of sputum, in preparation for recovery of mycobacterium.^[42] It also displays significant antiviral activity against the influenza A viruses.^[43]

Acetylcysteine has bactericidal properties and breaks down bacterial biofilms of clinically relevant pathogens including *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Enterococcus faecalis*, *Enterobacter cloacae*, *Staphylococcus epidermidis*, and *Klebsiella pneumoniae*.^[44]

Other uses

Acetylcysteine has been used to complex palladium, to help it dissolve in water. This helps to remove palladium from drugs or precursors synthesized by palladium-catalyzed coupling reactions.^[45] *N*-acetylcysteine can be used to protect the liver.^[46]

Side effects

The most commonly reported adverse effects for IV formulations of acetylcysteine are rash, urticaria, and itchiness.^[17] Up to 18% of patients have been reported to experience anaphylaxis reaction, which are defined as rash, hypotension, wheezing, and/or shortness of breath. Lower rates of anaphylactoid reactions have been reported with slower rates of infusion.

Adverse effects for inhalational formulations of acetylcysteine include nausea, vomiting, stomatitis, fever, rhinorrhea, drowsiness, clamminess, chest tightness, and bronchoconstriction. Although infrequent, bronchospasm has been reported to occur unpredictably in some patients.^[47]

Adverse effects for oral formulations of acetylcysteine have been reported to include nausea, vomiting, rash, and fever.^[47]

Large doses in a mouse model showed that acetylcysteine could potentially cause damage to the heart and lungs.^[48] They found that acetylcysteine was metabolized to *S*-nitroso-*N*-acetylcysteine (SNOAC), which increased blood pressure in the lungs and right ventricle of the heart (pulmonary artery hypertension) in mice treated with acetylcysteine. The effect was similar to that observed following a 3-week exposure to an oxygen-deprived environment (chronic hypoxia). The authors also found that SNOAC induced a hypoxia-like response in the expression of several important genes both *in vitro* and *in vivo*.

The implications of these findings for long-term treatment with acetylcysteine have not yet been investigated. The dose used by Palmer and colleagues was dramatically higher than that used in humans, the equivalent of about 20 grams per day.^[48] Nonetheless, positive effects on age-diminished control of respiration (the hypoxic ventilatory response) have been observed previously in human subjects at more moderate doses.^[49]

Although *N*-acetylcysteine prevented liver damage in mice when taken before alcohol, when taken four hours after alcohol it made liver damage worse in a dose-dependent fashion.^[50]

Pharmacology

Pharmacodynamics

Acetylcysteine serves as a prodrug to L-cysteine, a precursor to the biologic antioxidant glutathione. Hence administration of acetylcysteine replenishes glutathione stores.^[51]

- Glutathione, along with oxidized glutathione (GSSG) and *S*-nitrosoglutathione (GSNO), have been found to bind to the glutamate recognition site of the NMDA and AMPA receptors (via their γ -glutamyl moieties), and may be endogenous neuromodulators.^{[52][53]} At millimolar concentrations, they may also modulate the redox state of the NMDA receptor complex.^[53] In addition, glutathione has been found to bind to and activate ionotropic receptors that are different from any other excitatory amino acid receptor, and which may constitute *glutathione receptors*, potentially making it a neurotransmitter.^[54] As such, since *N*-acetylcysteine is a prodrug of glutathione, it may modulate all of the aforementioned receptors as well.
- Glutathione also modulates the NMDA receptor by acting at the redox site.^{[34][55]}

L-cysteine also serves as a precursor to cystine, which in turn serves as a substrate for the cystine-glutamate antiporter on astrocytes; hence there is increasing glutamate release into the extracellular space. This glutamate in turn acts on mGluR_{2/3} receptors, and at higher doses of acetylcysteine,

mGluR₅.^{[56][57]}

Acetylcysteine also possesses some anti-inflammatory effects possibly via inhibiting NF-κB and modulating cytokine synthesis.^[34]

Pharmacokinetics

Acetylcysteine is extensively liver metabolized, CYP450 minimal, urine excretion is 22–30% with a half-life of 5.6 hours in adults and 11 hours in newborns.

Chemistry

Acetylcysteine is the *N*-acetyl derivative of the amino acid L-cysteine, and is a precursor in the formation of the antioxidant glutathione in the body. The thiol (sulfhydryl) group confers antioxidant effects and is able to reduce free radicals.

N-acetyl-L-cysteine is soluble in water and alcohol, and practically insoluble in chloroform and ether.^[58]

It is a white to white with light yellow cast powder, and has a p*K*_a of 9.5 at 30 °C.^[5]

Dosage forms

Acetylcysteine is available in different dosage forms for different indications:

- Solution for inhalation (Assist, Mucomyst, Mucosil) – inhaled for mucolytic therapy
- Intravenous injection (Assist, Parvolex, Acetadote) – treatment of paracetamol/acetaminophen overdose
- Nebulized as an inhaled vapor, particularly in the treatment of cystic fibrosis and other acute pulmonary conditions
- Oral solution – various indications
- Effervescent tablets
- Ocular solution – for mucolytic therapy
- Tablets – sometimes in a sustained release formula sold as a nutritional supplement
- Capsules

The IV injection and inhalation preparations are, in general, prescription only, whereas the oral solution and the effervescent tablets are available over the counter in many countries. Acetylcysteine is available as a health supplement in the United States, typically in capsule form.

Society and culture

NAC was first studied as a drug in 1963. Amazon removed NAC for sale in the US in 2021, due to claims by the FDA of it being classified as a drug rather than a supplement.^{[59][60][61][62]} As of 21 April 2022, the FDA released draft guidance on FDA's policy regarding products labeled as dietary supplements that contain *N*-acetyl-L-cysteine.^[63]

NAC was studied as a drug and is today used as a medicine. It has also been sold as a dietary supplement within the United States prior to the advent of the Dietary Supplement Health Education Act (DSHEA 1994). The American Herbal Products Association (AHPA) and others have provided the FDA with details regarding NAC products sold before 15 October 1994. Additionally, NAC itself is found in a variety of foods (garlic, onions, asparagus, and others).

In 2020 FDA sent warning letters to several companies regarding the use of NAC in dietary supplements. In those letters FDA noted that NAC could not be marketed as a dietary supplement because NAC had NOT been marketed as a food or dietary supplement prior to its approval as a drug. FDA had confirmed in response to two citizen petitions (CRN and NPA) that NAC is excluded from the definition of a dietary supplement. FDA had not yet reached a decision, however, regarding a petitioner's (NPA) request to issue a regulation that would permit the use of NAC in dietary supplements. On April 21, 2022, the FDA announced the availability of a draft guidance on FDA's policy regarding products labeled as dietary supplements that contain *N*-acetyl-L-cysteine. The draft guidance, when finalized, will explain the agency's intent to exercise enforcement discretion with respect to the sale and distribution of certain NAC-containing products that are labeled as dietary supplements. The FDA has asked for comments on its NAC Guidance and has stated that they will use enforcement discretion with respect to NAC supplements.

Research

While many antioxidants have been researched to treat a large number of diseases by reducing the negative effect of oxidative stress, acetylcysteine is one of the few that has yielded promising results, and is currently already approved for the treatment of paracetamol overdose.^[64]

- In mouse mdx models of Duchenne's muscular dystrophy, treatment with 1–2% acetylcysteine in drinking water significantly reduces muscle damage and improves strength.^[64]
- It is being studied in conditions such as autism, where cysteine and related sulfur amino acids may be depleted due to multifactorial dysfunction of methylation pathways involved in methionine catabolism.^[65]
- Animal studies have also demonstrated its efficacy in reducing the damage associated with moderate traumatic brain or spinal injury, and also ischaemia-induced brain injury. In particular, it has been demonstrated to reduce neuronal losses and to improve cognitive and neurological outcomes associated with these traumatic events.^[35]
- It has been suggested that acetylcysteine may help people with Samter's triad by increasing levels of glutathione allowing faster breakdown of salicylates, although there is no evidence that it is of benefit.^[66]
- Small studies have shown acetylcysteine to be of benefit to people with blepharitis.^[67] It has been shown to reduce ocular soreness caused by Sjögren's syndrome.^[68]
- It has been shown that *N*-acetylcysteine may protect the human cochlea from subclinical hearing loss caused by loud noises such as impulse noise.^[69] In animal models, it reduced age-related hearing loss.
- It has been shown effective in the treatment of Unverricht-Lundborg disease in an open trial in four patients. A marked decrease in myoclonus and some normalization of somatosensory evoked potentials with acetylcysteine treatment has been documented.^{[70][71]}
- Addiction to certain addictive drugs (including cocaine, heroin, alcohol, and nicotine) is correlated with a persistent reduction in the expression of excitatory amino acid transporter 2 (EAAT2) in the nucleus accumbens (NAcc);^[41] the reduced expression of EAAT2 in this region is implicated in addictive drug-seeking behavior.^[41] In particular, the long-term dysregulation of glutamate

neurotransmission in the NAcc of addicts is associated with an increase in vulnerability to relapse after re-exposure to the addictive drug or its associated drug cues.^[41] Drugs that help to normalize the expression of EAAT2 in this region, such as *N*-acetylcysteine, have been proposed as an adjunct therapy for the treatment of addiction to cocaine, nicotine, alcohol, and other drugs.^[41]

- It is being tested for the reduction of hangover symptoms, but the clinical trial results are still being evaluated.^[72]
- A double-blind placebo controlled trial of 262 patients has shown NAC treatment was well-tolerated and resulted in a significant decrease in the frequency of influenza-like episodes, severity, and length of time confined to bed.^[73]

COVID-19

NAC is being considered as a possible treatment for COVID-19.^{[74][75][76]}

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External links

- "Acetylcysteine" (https://druginfo.nlm.nih.gov/drugportal/name/acetylcysteine). *Drug Information Portal*. U.S. National Library of Medicine.
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