

mentopin[®]

Acetylcysteine 200

Acetylcysteine 600

EFFERVESCENT TABLET

Brand or Product Name

Mentopin Acetylcysteine 200mg Effervescent Tablet
Mentopin Acetylcysteine 600mg Effervescent Tablet

Name and Strength of Active Substance(s)

Mentopin Acetylcysteine 200mg Effervescent Tablet contains 200mg acetylcysteine.
Mentopin Acetylcysteine 600mg Effervescent Tablet contains 600mg acetylcysteine.

Product Description

Mentopin Acetylcysteine 200mg Effervescent Tablet:
Round, white tablet with a smooth and faultless surface.
Mentopin Acetylcysteine 600mg Effervescent Tablet:
Round, white tablets with a smooth and faultless surface and a break-mark on one side.

Pharmacodynamics

Acetylcysteine exerts its mucolytic action through its free sulfhydryl group, which opens the disulfide bonds and lowers mucus viscosity. This action increases with increasing pH and is most significant at pH 7 to 9. The mucolytic action of acetylcysteine is not affected by the presence of DNA. N-acetylcysteine has been demonstrated to cause a decrease in sputum consistency, to facilitate easier expectoration, and to increase sputum volume. Bronchial mucus is composed of over 95% water; however, the physical characteristics of the mucus are due to glycoproteins. These glycoproteins bind to each other by way of disulfide bonds and give the mucus viscosity. N-acetylcysteine ruptures these disulfide bonds causing depolymerization and a rapid decrease in mucus viscosity. It also produces an irritative bronchorrheic effect on the mucosa, stimulating mucociliary clearance; this irritative effect may cause bronchospasm, thus acetylcysteine is not recommended in asthmatics.

Pharmacokinetics

Absorption

Absorption of acetylcysteine is rapid following oral administration, but the bioavailability is only 6-10% due to extensive first pass metabolism.
Oral bioavailability is similar for a single 600-mg dose and three 200-mg doses.
Peak plasma levels of acetylcysteine occur approximately one hour following oral administration.

Distribution

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.
Following a 100-mg oral dose, 48% was present in lung tissue.

Metabolism

Acetylcysteine undergoes extensive metabolism in the liver and intestinal wall.

Acetylcysteine undergoes rapid deacetylation in vivo to yield cysteine or oxidation to yield diacetylcysteine. Following deacetylation in the liver, it enters the normal metabolic pathway of the amino acid cysteine. An appreciable elevation in total serum sulfhydryl concentration occurs.

Elimination

Renal Excretion: 22% to 30% Faeces: 3%
Total Body Clearance: 6.5 L/hour (healthy subjects)
The mean terminal half-life is approximately 6 hours.

Indication

Treatment of respiratory affections characterized by thick & viscous hypersecretions: Acute bronchitis, chronic bronchitis and its exacerbations, pulmonary emphysema, mucoviscidosis & bronchiectasis.

Recommended Dosage

Mentopin Acetylcysteine 200mg Effervescent Tablet: **Adults:**
200mg 3 times a day.

Mentopin Acetylcysteine 600mg Effervescent Tablet: **Adults:**
600 mg daily as a single dose.

Dissolve content of an effervescent tablet in a glass of water and drink immediately.
The duration of treatment should be 5 to 10 days in the acute treatment, whereas it may be continued in the chronic states for several months, according to the advice of the doctor.

Adult age: 12 years onwards

Mode of Administration

Oral

Contraindications

It is contraindicated in patients with hypersensitivity to acetylcysteine, or any of the excipients.
Contraindicated in children under 2 years of age. Adult age: 12 years onwards

Warnings and Precautions

Patients suffering from bronchial asthma must be strictly controlled during the therapy; should bronchospasm occur, the treatment must immediately be suspended. Caution should be taken in patient suffering from or with a history of peptic ulcer. The possible presence of a sulphurous odour does not indicate an alteration of the product but is a characteristic of the active ingredient contained in this preparation. It is prefer not to mix other drugs with the Mentopin Acetylcysteine solution.

Interactions with Other Medicaments

No cases of drug-drug interaction are described in literature for acetylcysteine by oral use.
Statement on Usage During Pregnancy and Lactation

Pregnancy

No adequate and well-controlled studies have been done in pregnant women. Therefore, acetylcysteine should be used during pregnancy only when clearly needed.

Lactation

It is not known whether or not acetylcysteine passes into breast milk. Until more data is available, use caution when considering the use of acetylcysteine in lactating women.

Adverse Effects / Undesirable 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.

Immune System Disorders:

Anaphylactic / anaphylactoid reaction

Skin and Subcutaneous Tissue Disorders:

Severe cutaneous adverse reaction (SCAR) e.g. erythema multiforme, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). In most of these cases reported at least one other drug was administered at the same time, which may have possibly enhanced the described mucocutaneous effects.

Overdose and Treatment

There is no specific antidote for acetylcysteine and treatment is symptomatic. General supportive measures should be carried out and if necessary, according to the symptoms.

Storage Conditions

Store below 30°C

Dosage Forms and Packaging

Available Mentopin Acetylcysteine 200mg Effervescent Tablet: Pack in aluminium seal foil (pack of 2 x 5’s, 2 x 10’s).
Mentopin Acetylcysteine 600mg Effervescent Tablet:
Pack in aluminium seal foil (pack of 2 x 5’s, 2 x 10’s).

Name and Address of Manufacturer

Hermes Arzneimittel GmbH
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Name and Address of Product Registration Holder

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