Size : 165x120 mm

ACEVIZ

Acetylcysteine Powder for Oral Solution 600 mg

Product Name
ACEVIZ (Acetylcysteine Powder for Oral Solution 600 mg)

Name and Strength of Active Substance(s)
Acetylcysteine 600 mg

Product Description
White to off-white, granular powder after reconstitution in water form a clear solution.

Pharmacodynamics **& Pharmacokinetics**
Pharmacodynamics
Pharmacotherapeutic group: Mycolytics, ATC code: R05CB01
N-acetyl-L-cysteine (NAC), the active ingredient in Acetylcysteine 600 mg Powder for Oral Solution exerts an intense mucolytic-fluidizing action on mucous and mucopurulent secretions by depolymerizing the mucoproteic complexes and the nucleic acids which confer viscosity to the vitreous and purulent component of the sputum and other secretions.
Furthermore, acetylcysteine exerts a direct antioxidant action, having a free thiol (- SH) nucleophilic group that is able to interact directly with electrophilic groups of oxidant radicals. Of particular interest is the recent finding that acetylcysteine protects α1-antitrypsin enzyme inhibiting elastase from inactivation by hypochlorous acid (HOCl), a powerful oxidant agent produced by the myeloperoxidase enzyme of activated phagocytes. Due to its molecular structure, acetylcysteine can readily cross cell membranes. Inside the cell, NAC is deacetylated to L-cysteine, an amino acid essential for glutathione synthesis (GSH).
GSH is a highly reactive tripeptide found ubiquitously in the various tissues of animals and is essential for the maintenance of functional capacity as well as cellular morphological integrity. It is the most important protective intracellular mechanism against oxidant radicals, both exogenous and endogenous, as well as toward numerous cytotoxic substances.
These features make Acetylcysteine 600 mg Powder for Oral Solution particularly suitable for the treatment of acute and chronic affections of the respiratory system, characterised by thick, viscous mucous and mucopurulent secretions.
There is no evidence on the efficacy and safety of mucolytic s including acetylcysteine in acute bronchitis.
Pharmacokinetics
Absorption
Following oral administration, acetylcysteine is rapidly and almost completely absorbed and metabolised in the liver to cysteine (the pharmacologically active metabolite), diacetylcysteine, cysteine and further mixed disulphides.
Distribution
Due to the high first-pass effect, the bioavailability of orally administered acetylcysteine is very low (approximately 10%). In humans, maximum plasma concentrations are achieved after 1-3 hours with the maximum plasma concentration of the metabolite cysteine in the range of approximately 2µmol/l. The protein binding of Acetylcysteine was determined to be about 50%.
Biotransformation
Acetylcysteine and its metabolites occur in three different forms in the organism: partially in free form, partially bound to proteins via labile disulphide bonds and partially as incorporated amino acid. Acetylcysteine is excreted almost exclusively in the form of inactive metabolites (inorganic sulphates, diacetylcysteine) via the kidneys. The plasma half-life of Acetylcysteine is approximately 1 hour and is mainly determined by the rapid hepatic biotransformation. Impaired hepatic function therefore leads to prolonged plasma half-lives of up to 8 hours.
Elimination
Pharmacokinetic studies with intravenous administration of acetylcysteine revealed a distribution volume of 0.47 1/kg (in total) or 0.59 l/kg (reduced acetylcysteine); the plasma clearance was determined to be 0.11 l/h/kg (in total) and 0.84 l/h/kg (reduced acetylcysteine), respectively. The elimination half-life after intravenous administration is 30-40 minutes while excretion follows three-phase kinetics (alpha, beta and terminal gamma phase).
Acetylcysteine crosses the placenta and is detected in cord blood. No information is available regarding excretion in breast milk.No knowledge is available concerning the behaviour of acetylcysteine at the blood- brain barrier in humans

Indication
All respiratory tract diseases leading to the formation of thick secretions difficult to be expectorated, such as acute and chronic bronchitis, laryngitis, sinusitis, tracheitis, influenza, bronchial asthma and (as complementary treatment) mucoviscidosis.

Recommended Dosage
Adults: 1 sachet (600mg) per day.
Route of administration: Oral
Method of administration
Dissolve the contents of one sachet completely in a glass containing a little water just before use, stirring as needed with a teaspoon.

Contraindications
Contraindicated in children below two (2) years of age.
Hypersensitivity to the active substance or to any of the excipients.

Warnings and Precautions
JAUHKAN UBAT DARIPADA CAPAIAN KANAK-KANAK
'KEEP OUT OF REACH OF CHILDREN"
Please consult your pharmacist/doctor before taking this product.
Patients with bronchial asthma should be closely monitored during therapy; if' bronchospasm occurs, treatment with Acetylcysteine Powder for Oral Solution should be discontinued immediately.
Administration of acetylcysteine, especially at the beginning of treatment, may liquefy bronchial secretions and, at the same time, increase their volume. If the patient is unable to expectorate efficiently, to avoid retention of secretions postural drainage and tracheal suction should be used.
Acetylcysteine can cause interference with the colorimetric assay method for the determination of salicylates.
Acetylcysteine can interfere with tests for ketones in urine.

Interactions with Other Medicaments
Antitussive drugs and acetylcysteine should not be administered concomitantly because reducing the cough reflex may lead to a build-up of bronchial secretions.
Activated charcoal may reduce the effect of acetylcysteine.
It is advisable not to mix Acetylcysteine Powder for Oral Solution with other medicinal products.
In vitro tests have shown that when cephalosporin antibiotics and acetylcysteine are mixed, there is a degree of antibiotic inactivation. It is precautionary to advise the administration of oral antibiotics at least two hours before or after acetylcysteine.
Concurrent administration of nitroglycerin and acetylcysteine causes significant hypotension and leads to temporal artery dilation with possible onset of headache.
If concurrent administration of nitroglycerin and acetylcysteine is required, patients should be monitored and warned for hypotension that can be severe and accompanied by a headache.

Statement on usage during pregnancy and lactation
Pregnancy
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of Acetylcysteine Powder for Oral Solution during pregnancy.
Lactation
There is insufficient information on the excretion of acetylcysteine in human milk. A risk to the newborns/infants cannot be excluded.

Side Effects

Immune System Disorders:

Anaphylactic / anaphylactoid reaction

Skin and Subcutaneous Tissue Disorders:

Severe cutaneous adverse reactions (SCAR) e.g. erythema multiforme, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). In most of these cases reported atleast one other drug was administered at the same time, which may have possibly enhanced the described mucocutaneous effects.
Adverse reactions are listed below, by system organ class and frequency.

System Organ Class	Frequency / Adverse Reactions			
	Uncommon (≥1/1,000, < 1/100)	Rare (≥1/10,000, < 1/1,000)	Very rare (< 1/10,000)	Not Known
Immune system disorders	Hypersensitivity		Anaphylactic shock, anaphylactic/ anaphylactoid reaction	
Nervous system disorders	Headache			
Ear and labyrinth disorders	Tinnitus			
Cardiac disorders	Tachycardia			
Vascular disorders	Hypotension		Haemorrhage	
Respiratory, thoracic and mediastinal disorders	Hypotension	Bronchospasm, dyspnoea		
Gastrointestinal disorders	Vomiting, diarrhoea, stomatitis, abdominal pain, nausea	Dyspepsia		
Skin and subcutaneous tissue disorders	Urticaria, rash, angioedema, pruritus			
General disorders and administration site conditions	Fever			Oedema of the face

In case of recurrence skin and mucosal lesions, medical advice should be sought at once and the use of acetylcysteine terminated immediately.
A decreased blood platelet aggregation in the presence of acetylcysteine has been confirmed by various studies. The clinical relevance has not yet been clarified to date.

Overdose and Treatment
An acute overdose of acetylcysteine can cause gastrointestinal symptoms such as nausea, vomiting and diarrhoea.

Treatment of Overdose
Treatment of overdose is to be symptomatic and supportive treatment as indicated by the patient's clinical condition.

Storage Conditions
Store at temperature not exceeding 30°C.
This product should be used as a single use.
Jauhkan daripada capaian kanak-kanak.
Keep out of reach of children.

Dosage forms and packaging available
Powder for oral solution
3g x 30 sachets in a carton.

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XL

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