Acetylcysteine

Exflem®

600 mg Granules for Solution
Mucolytic

℞

FORMULATION
Each sachet contains:
Acetylcysteine ..... 600 mg

PHARMACOLOGIC CATEGORY
Mucolytic

PRODUCT DESCRIPTION
Acetylcysteine (Exflem®) 600 mg Sachets are white granules in sachet.

CLINICAL PHARMACOLOGY
Pharmacodynamics
Acetylcysteine, the N-acetyl derivative of the naturally occurring amino acid, L-cysteine, is a mucolytic agent, an antidote for paracetamol poisoning and a sulfhydryl donor. Acetylcysteine has an intense mucolytic action on mucoid and mucopurulent secretions due to its ability to split disulfide bonds in mucous glycoprotein altering their configuration to improve flow characteristics thus reducing the viscosity of mucus.

Acetylcysteine has antioxidant action because of its nucleophilic free thiol (-SH) group that directly interacts with electrophilic groups of the oxidative radicals. Acetylcysteine protects α_1-antitrypsin (an enzyme that inhibits elastase) from inactivation by hypochlorous (HOCl) acid. Hypochlorous acid (HOCl) is a potent oxidative agent produced by the myeloperoxidase enzyme of activated phagocytes. These activities make acetylcysteine particularly appropriate for the treatment of acute and chronic conditions of the respiratory system characterized by mucoid and mucopurulent dense and viscous secretions.

Pharmacokinetics
Acetylcysteine is rapidly absorbed from the gastrointestinal tract and transported to the liver via the portal circulation, where it undergoes extensive first-pass metabolism. The oral bioavailability of acetylcysteine varies between 6 and 10%. Peak plasma concentrations are observed approximately 0.5 to 1 hour after oral doses of 200 to 600 mg.

Acetylcysteine may be present in plasma as the parent compound or as various oxidized metabolites such as N-acetylcysteine, N,N-diacetylcysteine and L-cysteine. L-cysteine itself is metabolized to glutathione, protein, taurine and sulfate. Renal clearance may account for about 30% of total body clearance. The terminal half-life of total acetylcysteine is 6.25 hours after oral dosing.

INDICATIONS
Acetylcysteine is used for its mucolytic activity in respiratory disorders associated with productive cough and thick viscous hypersecretion such as acute bronchitis, chronic bronchitis and its exacerbation, pulmonary emphysema, cystic fibrosis, and bronchiectasis.

DOSAGE AND ADMINISTRATION
Adults and Children over 14 Years Old:
Orally, contents of 1 sachet once a day, or, as prescribed by a physician.

Duration of treatment:
- Acute Disorders: 5 to 10 days
- Chronic Disorders: May be continued for several months, according to the advise of a physician.

Directions for use:
- Empty contents of one (1) sachet into a mug.
- Dissolve the granules in about ½ glass (100 mL) of water.
- Stir until the solution clears.
- Consume entire drink.
- Acetylcysteine solution should not be mixed with other medicines to avoid interaction.

CONTRAINDICATION
Hypersensitivity to any ingredient of the product.

WARNINGS AND PRECAUTIONS
After proper administration of acetylcysteine, an increased volume of liquefied bronchial secretions may occur. If the patient cannot expectorate efficiently, postural drainage and bronchoaspiration must be used to avoid retention of secretions.

Carefully observe asthmatics under treatment with acetylcysteine. If bronchospasm occurs, discontinue acetylcysteine immediately.

Use with caution in patients with a history of peptic ulcer disease because drug-induced nausea and vomiting may increase the risk of gastrointestinal hemorrhage in patients predisposed to the condition and because of a theoretical risk that mucolytics may disrupt the gastric mucosal barrier.

The presence of a sulfur-like odor does not indicate an alteration of the product but is a characteristic of the drug substance contained in the preparation.

Phenylketonurics - This product contains phenylalanine as one of the metabolites of aspartame.

DRUG INTERACTIONS
Based on acetylcysteine's mechanism of action, the concomitant administration of acetylcysteine and other drugs that may interact with thiol group (e.g., nitroglycerin) is not recommended.

STATEMENT ON USAGE FOR HIGH RISK GROUPS
Pregnancy: **Pregnancy Category B.** The safe use of acetylcysteine during pregnancy has not been established. Acetylcysteine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known whether acetylcysteine is excreted in human milk. Therefore, do not administer to breastfeeding women unless, in the opinion of a physician, the potential benefit of the product justifies the possible risk.

ADVERSE EFFECTS
Generally, acetylcysteine is well tolerated. Hypersensitivity reactions including urticaria, pruritus, angioedema, bronchospasm, hypotension or hypertension may occasionally occur. Other adverse effects reported include headache, flushing, nausea, vomiting, fever, syncope, drowsiness, tinnitus, chills, sweating/clamminess, chest tightness, arthralgia, blurred vision, disturbances of liver function, acidosis, convulsions, bronchoconstriction, irritation to the trachea and bronchial tracts, and cardiac or respiratory arrest. Hemoptysis, rhinorrhea, and stomatitis have also been reported.

OVERDOSE AND TREATMENT
Symptoms of acetylcysteine overdose include rash, flushing, nausea, vomiting, bronchospasm, edema, tachycardia, hypotension, respiratory depression, hemolysis, disseminated intravascular coagulation, and renal failure.

In case of overdosage, discontinue acetylcysteine and institute appropriate symptomatic and supportive therapy (e.g., postural drainage and bronchoaspiration).

AVAILABILITY: Box of 30 sachets

ADVERSE DRUG REACTION REPORTING STATEMENT
For suspected adverse drug reaction,seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

CAUTION
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

Keep the product out of reach and sight of children.

STORE BELOW 25°C IN A DRY PLACE

Manufactured by Neutec Ilac San. Tic. A.S.
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Reg. IPOPHIL
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