Direct Healthcare Professional Communication

Jan 2025

N-acetyl-cysteine containing medicines: Reminder of the proper use of IV and inhalation preparations

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance (PVGA) at the Egyptian drug authority (EDA) would like to Remind you **about the proper use of IV and inhalation preparations of N-acetyl-cysteine containing medicines.**

Summary

- IV and inhalation preparations of N-acetyl-cysteine containing medicines should be administered as described in the product information labels approved by Egyptian Drug Authority (EDA).

- IV preparations are indicated as an antidote to prevent or lessen hepatic injury which may occur following the ingestion of a potentially hepatotoxic quantity of acetaminophen.

- Inhalation preparations are indicated as adjuvant therapy for patients with abnormal, viscid, or inspissated mucous secretions in such conditions as: chronic bronchopulmonary disease (chronic emphysema, emphysema with bronchitis, chronic asthmatic bronchitis, tuberculosis, bronchiectasis and primary amyloidosis of the lung); acute bronchopulmonary disease (pneumonia, bronchitis, tracheobronchitis); pulmonary complications of cystic fibrosis; post tracheostomy care; pulmonary complications associated with surgery; use during anesthesia; post-traumatic chest conditions; atelectasis due to mucous obstruction; diagnostic bronchial studies (bronchograms, bronchospirometry and bronchial wedge catheterization).

- Treatment with inhalation preparations of N-acetyl-cysteine containing medicines is contraindicated in children under 2 years' old.

- Some preparations of N-acetyl-cysteine IV infusion may contain benzyl alcohol as excipient are contraindicated in neonates less than 4 weeks old due to gasping syndrome & contraindicated in pregnant women & nursing mothers.

- Health care professionals should be sticky to the dosage and method of administration of IV and inhalation preparations of N-acetyl-cysteine containing medicines.

Background on the safety concern

For IV preparations:

N-acetyl-L-cysteine (NAC), is a cysteine derivative with a free nucleophilic thiol group (-SH), which can interact directly with the electrophilic groups of oxidising radicals. Additionally, the molecule's structure allows it to easily cross cellular membranes. Inside the cell, NAC is de-acetylated and L-cysteine becomes available - this amino acid is essential for glutathione synthesis (GSH). GSH is a highly reactive tripeptide that is ubiquitously present in the tissues of animals. It is essential for maintaining the cell's capacity to function and its morphological integrity, because it is the most important intra-cellular defence mechanism against oxidising radicals (endogenous or exogenous) and against many cytotoxic substances. Because of its properties as glutathione precursor and antioxidant, NAC is used as an alternative substrate and helps protect cells against the action of harmful agents that, by progressively depleting GSH stores, would exert their cytotoxic action in full, as in the case of paracetamol overdose, which can lead to liver failure, encephalopathy and death. The administration of N-acetylcysteine increases glutathione stores and, therefore, the ability to deal with increased demand and prevent damage to the liver. The antidote treatment is the more effective the earlier therapy is started.

For inhalation preparations:

Acetylcysteine, is neither an enzyme nor a detergent. The viscosity of pulmonary mucous secretions depends on the concentrations of mucoprotein and to a lesser extent deoxyribonucleic acid (DNA). The latter increases with increasing purulence owing to cellular debris. The mucolytic action of acetylcysteine is related to the sulfhydryl group in the molecule. This group probably 'opens' disulfide linkages in mucus, thereby lowering the viscosity.

Annexes:

Product information of IV and inhalation preparations of N-acetyl-cysteine containing medicines.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://vigiflow-eforms.who-umc.org/eg/med
QR Code:

PO Box: 11451

Hotline: 15301