94467-ACETYLCYSTEINE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation

Name: Acetylcysteine
Code: 94467

1.2 Synonyms

Acetylcysteinum; N-Acetylcysteine; Acetylcysteine; N-Acetyl-3-mercaptoalanine, Acetyl-n l-cysteine.

2. DESCRIPTION

Appearance: Crystalline powder or crystals.
Colour: White (powder) or colourless (crystals).
Odour: Slight odour of acetic acid.
Deliquescent.

3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: $C_5H_9NO_3S$
CAS: 616-91-1
Molecular weight: 163,2 g/mol

4. PHYSICO-CHEMICAL DATA

See detailed specifications in analysis bulletin.

Solubility: Soluble in 8 p. water and 2 p. alcohol; practically insoluble in chloroform and ether.

Melting point: 104–110°C.

5. PROPERTIES/USES

ACTIVE PHARMACEUTICAL INGREDIENT.

Acetylcysteine is a mucolytic agent that reduces the viscosity of mucous secretions, likely by breaking the disulphide bonds in mucoproteins.
It is used to treat cystic fibrosis and other processes affecting the respiratory tract with production of very viscous mucous secretion, chronic bronchitis, asthma or tracheostomy patients.

It is also indicated in the treatment of paracetamol poisoning, as it acts by donating sulphydryl groups and protecting the liver from the toxic metabolites of paracetamol, restoring liver deposits of reduced glutathione and/or serving as a substrate for their elimination.

6. DOSAGE

Orally:

- In the form of granules dissolved in water, in doses of 200 mg, three times a day.
- A dosage of 200 mg/day is recommended for children under 2 years of age and 200 mg twice daily in children 2–6 years of age.

7. REMARKS

STORAGE:
Store at room temperature (25±2ºC), in a cool, dry place, away from sunlight, in a hermetically sealed container.

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

8. BIBLIOGRAPHY

Monografías Farmacéuticas. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).