Approved Professional Information for Medicines for Human Use: Amuco 200 mg effervescent tablets

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

AMUCO 200 effervescent tablets.

COMPOSITION

Each effervescent tablet contains 200 mg N-Acetylcysteine.

Excipients: citric acid, anhydrous; orange flavor 00285, purified water, sodium carbonate anhydrous; sodium hydrogen carbonate; sorbitol 0,28 % m/m and artificial sweeteners: saccharin sodium 15 mg/tablet and sodium cyclamate 20 mg/tablet.

Contains sugar (sorbitol 7 mg/tablet).

CATEGORY AND CLASS

A 10.2.2 Medicines acting on the respiratory system – other.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties:

N-Acetylcysteine is a mucolytic agent that reduces the viscosity of non-infected secretions in the respiratory tract probably by the splitting of disulphide bonds in mucoproteins.

Pharmacokinetic properties:

Absorption:

Acetylcysteine is rapidly absorbed from the gastrointestinal tract.

Distribution:

Peak plasma concentrations are reached after 1-3 hours with the maximum plasma concentration of the metabolite cysteine in the range of approximately 2 µmol/l. Oral bioavailability is low, approximately 10 % due to the high first-pass metabolism.

Biotransformation:

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.

Elimination:

Acetylcysteine is eliminated, mainly through the kidneys in the form of inactive metabolites (inorganic sulphates, diacetylcysteine).

INDICATIONS

N-Acetylcysteine is used as a mucolytic in acute respiratory conditions for a maximum treatment period of 14 days.

CONTRAINDICATIONS

Hypersensitivity to N-Acetylcysteine or to any of the other ingredients of **AMUCO 200 OTC** (see COMPOSITION).

Children below two years of age.

Pregnancy and lactation (see HUMAN REPRODUCTION).

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WARNINGS AND SPECIAL PRECAUTIONS

AMUCO 200 should be used with caution in asthmatic patients and and the elderly with respiratory insufficiency. Mucolytics may disrupt the gastric mucosal barrier. It should therefore be used with caution in patients with a history of peptic ulceration.

Effects on ability to drive and use machines

AMUCO 200 may impair your ability to drive or operate machinery.

INTERACTIONS

Caution should be exercised when **AMUCO 200** is used concomitantly with a cough suppressant as congestion of secretions may occur due to the impaired cough reflex.

Tetracycline hydrochloride (with the exception of doxycycline) and other oral antibiotics must be administered separately of **AMUCO 200** and with an interval of at least two hours.

HUMAN REPRODUCTION

Safety during pregnancy and lactation has not been established.

It is not known whether N-Acetylcysteine is excreted in human milk. Mothers on **AMUCO 200** should not breastfeed their infants.

DOSAGE AND DIRECTIONS FOR USE

The effervescent tablets should be dissolved in a glass of water before use.

As a mucolytic:

Children:

- 2 – 5 years: 100 mg (½ effervescent tablet) two to three times daily.
- 6 – 14 years: 200 mg (1 effervescent tablet) twice daily.

Adults: 200 mg (1 effervescent tablet) two to three times daily.

SIDE-EFFECTS

Immune system disorders:

Less frequent: Anaphylaxis, allergic reactions (pruritus, urticaria, exanthema, rash, bronchospasticity, angioedema, tachycardia, hypertension and hypotension).

Metabolic disorders:

Less frequent: Acidosis.

Nervous system disorders:

Less frequent: Headache, convulsions, syncope.

Eye disorders:

Less frequent: Blurred vision.

Ear and labyrinth disorders:

Less frequent: Tinnitus.

Cardiac disorders:

Less frequent: Cardiac arrest.

Vascular disorders:

Less frequent: Flushing, sweating.

Respiratory, thoracic and mediastinal disorders:

Less frequent: Bronchospasm, rhinorrhoea, dyspnea, respiratory arrest.

Gastrointestinal disorders:

Less frequent: Nausea, vomiting, stomatitis, abdominal pain, diarrhoea, heartburn.

Hepato-biliary disorders:

Less frequent: Liver function disturbances.

Skin and subcutaneous tissue disorders:

Less frequent: Allergic dermatitis (skin rash or hives), urticaria.

Musculoskeletal, connective tissue and bone disorders:

Less frequent: Arthralgia.

General disorders and administration site conditions:

Less frequent: Chills and fever.

Investigations:

Less frequent: Acidosis.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENTS

See side-effects. Treatment should be symptomatic and supportive.

IDENTIFICATION

White, round plane tablets, with an orange smell.

PRESENTATION

White cylindrical polypropylene tube containing 8, 10, 12, 15, 20, 25, 30, 40 or 42 tablets sealed with a polyethylene cap containing silica gel in a unit carton.

Not all pack sizes may be marketed.

STORAGE INSTRUCTIONS

Store at or below 25 ºC in a cool dry place. Protect from light.

The container must be tightly closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

43/10.2.2/0510

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