PACKAGE INSERT: MUCATAK® 200 EFFERVESCENT TABLETS

Scheduling status: **S1**

Proprietary Name and Dosage Form:

MUCATAK® 200 Effervescent Tablets

Composition:

Each effervescent tablet contains: 200 mg Acetylcysteine.

Other ingredients are: Sodium hydrogencarbonate, citric acid (anhydrous), lemon aroma, liquid paraffin, magnesium stearate and purified water.

Contains aspartame as sweetening agent.

Sugar free.

Pharmacological Classification:

A 10.1 Medicines acting on the respiratory system – Others.

Pharmacological Action:

Pharmacodynamic properties:

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:

Acetylcysteine is well absorbed from the gastro-intestinal tract.

Studies indicate that peak plasma concentrations are reached within 0,5 to 1,0 hour following orally administered doses of 200 to 600 mg.

Acetylcysteine may be present in plasma and tissues as either the parent compound or as various metabolites such as cysteine, N-N-diacetylcysteine and N-acetylcysteine either free or bound to plasma proteins.

Acetylcysteine is extensively metabolised in the gut wall and liver.

The bio-availability after oral administration is approximately 10 %.

Renal clearance may account for 30 % of total body clearance.

Following oral administration, the mean terminal half-life of acetylcysteine was calculated to be 6,25 hours.

Indications:

MUCATAK 200 is used as a mucolytic in non-infected secretions of patients with cystic fibrosis and other respiratory conditions.

Contraindications:

Hypersensitivity to acetylcysteine or any of the ingredients of **MUCATAK 200**.
Children under the age of 2 years.
Pregnancy and lactation (see "Pregnancy and Lactation").

Warnings and Special Precautions:

MUCATAK 200 should be used with caution in asthmatic patients and in elderly patients with respiratory insufficiency.

MUCATAK 200 should be used with caution in patients with a history of gastric ulcers, since mucolytics may disrupt the gastric mucosal barrier.
MUCATAK 200 contains aspartame, which may be harmful for people with phenylketonuria.

Effects on ability to drive and use machines:
MUCATAK 200 may affect the ability to drive and to use machines.

Interactions:

Caution should be exercised when combining **MUCATAK 200** with a cough suppressant as congestion of secretions may occur as a result of the impaired cough reflex.
MUCATAK 200 must be administered separately from tetracycline hydrochloride (with the exception of doxycycline) and other oral antibiotics, with an interval of at least 2 hours.

Pregnancy and Lactation:

Safety and/or efficacy in pregnancy and lactation has not been established.
It is not known whether acetylcysteine crosses into breast milk. Mothers on **MUCATAK 200** should not breastfeed their infant.

Dosage and Directions for Use:

MUCATAK 200 effervescent tablets should be dissolved in a glass of water before administration.

As a mucolytic:

Children from 2 to 5 years of age: ½ effervescent tablet 2 to 3 times daily (equivalent to 200 to 300 mg N-acetylcysteine/day) for a maximum treatment period of 14 days.

Children from 6 to 14 years of age: 1 effervescent tablet twice daily (equivalent to 400 mg N-acetylcysteine/day) for a maximum treatment period of 14 days.

Adults and adolescents from 14 years of age: 1 effervescent tablet 2 to 3 times daily (equivalent to 400 to 600 mg N-acetylcysteine/day) for a maximum treatment period of 14 days.

Side Effects:

Immune system disorders:

*Less frequent: A*llergic reactions (pruritus, urticaria, exanthema, rash, bronchospasm, angioedema, tachycardia, hypotension and hypertension).

Anaphylactic reactions with shock in extreme cases.

Nervous system disorders:

Frequency unknown: Syncope, convulsions.

Eye disorders:

Frequency unknown: Blurred vision.

Ear and labyrinth disorder:

Less frequent: Tinnitus.

Cardiac disorders:

Frequency unknown: Cardiac arrest.

Vascular disorders:

Frequency unknown: Flushing, sweating.

Respiratory, thoracic and mediastinal disorder:

Less frequent: Dyspnoea, rhinorrhoea, bronchospasm.

Frequency unknown: Haemoptysis, respiratory arrest.

Gastrointestinal disorders:

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

Hepato-biliary disorders:
Frequency unknown: Disturbances of liver function.

Musculoskeletal, connective tissue and bone disorders:
Frequency unknown: Arthralgia.

General disorders and administration site conditions:
Less frequent: Headache, fever, chills.

Investigations:
Frequency unknown: Acidosis.

Known Symptoms of Overdosage and Particulars of its Treatment:
Treatment is supportive and symptomatic. (See "Side Effects").

Identification:
White, flat, round tablets, break-line on one side, characteristic odour of acetylcysteine and lemon aroma. Diameter: 18 mm; Height: 4,1 – 4,5 mm.

Presentation:
White aluminium or polypropylene (plastic) tubes with an inner white lining. Each tube is sealed with a white polyethylene (plastic) stopper which has an integrated silica gel adsorbent (integrated into the stopper). Each tube is contained in an outer cardboard carton and contains 25 effervescent tablets.

Storage Instructions:
Store at or below 25 °C in the original container and protect from light. Keep well-closed.
KEEP OUT OF REACH OF CHILDREN.

Registration Number:
44/10.1/0927

Name and Business Address of the Holder of the Certificate of Registration:
Actor Pharma (Pty) Ltd[1]
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