Professional information for MUCATAK 200 EFFERVESCENT TABLETS

SCHEDULING STATUS: S1

1. NAME OF THE MEDICINE

MUCATAK 200 EFFERVESCENT TABLETS (200 mg, effervescent tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains 200 mg acetylcysteine.

Excipients with known effects:

Contains sweetener: Each effervescent tablet contains 10 mg aspartame.

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

MUCATAK 200 EFFERVESCENT TABLETS should be dissolved in a glass of water before

administration.

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).

Paediatric population

Children from 6 to 14 years of age:

1 effervescent tablet twice daily (equivalent to 400 mg N-acetylcysteine/day).

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).

Method of administration

Oral administration.

Do not use continuously for more than 14 days without consulting a

doctor.

4.3 Contraindications

- Hypersensitivity to acetylcysteine or any of the ingredients of MUCATAK 200 EFFERVESCENT TABLETS (see section 6.1).
- Children under the age of 2 years.
- Pregnancy and lactation (see section 4.6).
- Active peptic ulceration.

4.4 Special warnings and precautions for use

Respiratory problems

MUCATAK 200 EFFERVESCENT TABLETS should be used with caution in asthmatic patients and

in elderly patients with respiratory insufficiency.

Bronchospasms may occur with the use of acetylcysteine as in MUCATAK 200 EFFERVESCENT TABLETS. If bronchospasm occurs, MUCATAK 200 EFFERVESCENT TABLETS should be discontinued immediately.

Bronchial secretions may become more fluid and increase in volume, in particular at the start of the treatment with MUCATAK 200 EFFERVESCENT TABLETS. When a patient is unable to cough up the secretions effectively, postural drainage and bronchoaspiration should be performed.

Gastric ulcers

MUCATAK 200 EFFERVESCENT TABLETS should be used with caution in patients with a history of gastric ulcers, especially when used concomitantly with other medicines known to irritate the mucous membrane of the gastrointestinal tract, since mucolytics may disrupt the gastric mucosal barrier.

Skin reactions

Serious skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome have very rarely been reported in temporal connection with the use of acetylcysteine as in MUCATAK 200 EFFERVESCENT TABLETS. If cutaneous or mucosal changes occur, immediate medical advice should be sought and the treatment with MUCATAK 200 EFFERVESCENT TABLETS should be discontinued immediately (see section 4.8).

Histamine intolerance

Caution is advised in patients with histamine intolerance. Treatment with MUCATAK 200 EFFERVESCENT TABLETS for longer periods should be avoided in such patients as MUCATAK 200 EFFERVESCENT TABLETS affects histamine metabolism and can result in symptoms of intolerance (e.g. headache, runny nose and itching) (see section 4.8).

Paediatric population

Mucolytic medicines may obstruct the airways of children under 2 years of age, due to the

physiological characteristics of the airways in this age group. The ability to cough up mucus may be limited. Therefore, MUCATAK 200 EFFERVESCENT TABLETS should not be used in children under 2 years of age (see section 4.3).

MUCATAK 200 EFFERVESCENT TABLETS contains aspartame

MUCATAK 200 EFFERVESCENT TABLETS contains aspartame, which may be harmful to patients with phenylketonuria (a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly). Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age.

MUCATAK 200 EFFERVESCENT TABLETS contains sodium

MUCATAK 200 EFFERVESCENT TABLETS contains 146,4 mg sodium per effervescent tablet, equivalent to 7,3 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. Caution is advised in patients on a sodium restricted diet.

4.5 Interaction with other medicines and other forms of interaction

- Caution should be exercised when combining MUCATAK 200 EFFERVESCENT TABLETS with a cough suppressant as congestion of secretions may occur as a result of the impaired cough reflex.
- MUCATAK 200 EFFERVESCENT TABLETS must be administered separately from tetracycline hydrochloride (with the exception of doxycycline) and other oral antibiotics, with an interval of at least 2 hours.
- Acetylcysteine as in MUCATAK 200 EFFERVESCENT TABLETS may enhance the vasodilatory effects of nitroglycerin. Caution is advised. If concurrent administration of nitroglycerin and MUCATAK 200 EFFERVESCENT TABLETS is required, patients should be monitored and warned for hypotension that can be severe and accompanied by a headache.
- Activated charcoal can decrease the effect of acetylcysteine as in MUCATAK 200 EFFERVESCENT TABLETS due to reduced absorption

- The dissolution (mixing) of MUCATAK 200 EFFERVESCENT TABLETS together with other medicines is not recommended.
- Acetylcysteine as in MUCATAK 200 EFFERVESCENT TABLETS may have an effect on the values of salicylates by colorimetric analysis.

  In urine tests, MUCATAK 200 EFFERVESCENT TABLETS can affect the results of determination of ketone bodies.

4.6 Fertility, 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 EFFERVESCENT TABLETS should not breastfeed their infant.

No data are available on the effects of MUCATAK 200 EFFERVESCENT TABLETS on fertility.

4.7 Effects on ability to drive and use machines

MUCATAK 200 EFFERVESCENT TABLETS may cause headache, convulsions and blurred vision, which may impair the ability to drive a vehicle or operate machinery (see section 4.8). Patients should be advised to exercise caution after taking MUCATAK 200 EFFERVESCENT TABLETS until the effects are known.

4.8 Undesirable effects

Immune system disorders

Less frequent: Allergic reactions (pruritus, urticaria, exanthema, rash, bronchospasm, angioedema).

Anaphylactic reactions with shock in extreme cases.

Nervous system disorders

Less frequent: Headache.

Frequency unknown: Syncope, convulsions.

Eye disorders

Frequency unknown: Blurred vision.

Ear and labyrinth disorders

Less frequent: Tinnitus.

Cardiac disorders

Less frequent: Tachycardia, hypertension.

Frequency unknown: Cardiac arrest.

Vascular disorders

Less frequent: Haemorrhage, hypotension.

Frequency unknown: Flushing, sweating.

Respiratory, thoracic and mediastinal disorders

Less frequent: Dyspnoea, rhinorrhoea, bronchospasm (predominantly in patients with hyper reactive bronchial system in association with bronchial asthma).

Frequency unknown: Haemoptysis, respiratory arrest.

Gastrointestinal disorders

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

Hepato-biliary disorders

Frequency unknown: Disturbances of liver function.

Skin and subcutaneous tissue disorders

Less frequent: Stevens-Johnson syndrome, and toxic epidermal necrolysis (TEN).

Musculoskeletal and connective tissue disorders

Frequency unknown: Arthralgia.

General disorders and administration site conditions

Less frequent: Fever, chills.

Frequency unknown: Oedema of the face.

Investigations

Frequency unknown: Acidosis.

Description of selected adverse reactions

The occurrence of serious skin reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in temporal association with the use of acetylcysteine, as contained in MUCATAK 200 EFFERVESCENT TABLETS.

In case of recurrent skin and mucosal lesions, medical advice should be sought at once and the use of MUCATAK 200 EFFERVESCENT TABLETS terminated immediately.

A decreased blood platelet aggregation in the presence of acetylcysteine as in MUCATAK 200 EFFERVESCENT TABLETS has been confirmed by various studies. The clinical relevance has not yet been clarified to date.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free).

4.9 Overdose

Overdoses may lead to gastrointestinal effects such as nausea, vomiting and diarrhoea.

Small children are at risk of hypersecretion (see section 4.4).

Treatment is supportive and symptomatic (see section 4.8).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 10.3 Medicines acting on the respiratory system – Others.

Pharmacotherapeutic groups: Mucolytics

ATC code: R05C B01

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

5.2 Pharmacokinetic properties

Absorption

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. The bioavailability after oral administration is approximately 10 %.

Distribution

The highest tissue concentrations of acetylcysteine are reached in the liver, kidneys and lungs.

Biotransformation

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

Acetylcysteine is extensively metabolised in the gut wall and liver. Impaired hepatic function

therefore leads to prolonged plasma half-lives of up to 8 hours.

Elimination

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aspartame (E 951)

Citric acid anhydrous

Lemon aroma

Liquid paraffin or magnesium stearate

Sodium hydrogen carbonate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months in polypropylene (plastic) tubes.

60 months in aluminium tubes.

Store at or below 30 °C.

6.4 Special precautions for storage

Keep well-closed.

Store in the original container and protect from light.

6.5 Nature and contents of container

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 either 10, 15, 20 or 25 effervescent tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Cipla Medpro (Pty) Ltd.

Building 9

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Mispel Street

Bellville

7530

Customer Care: 080 222 6662

8. REGISTRATION NUMBERS

MUCATAK 200 EFFERVESCENT TABLETS - 44/10.1/0927

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 26 October 2012

10. DATE OF REVISION OF THE TEXT

To be allocated.