SCHEDULING STATUS: S1

PROPRIETARY NAME: **MEDI-KEEL A® THROAT LOZENGES**

MEDI-KEEL A® HONEY AND LEMON THROAT LOZENGES

MEDI-KEEL A® BLACKCURRANT THROAT LOZENGES

(AND DOSAGE FORM) **(LOZENGE)**

COMPOSITION:

Each lozenge contains:

Benzocaine	12,0 mg
Cetylpyridinium chloride	1,5 mg

Contains sugar:

Sucrose	2,32 g
Liquid glucose	1,54 g

Tartrazine free

List of Excipients:

MEDI-KEEL A® THROAT LOZENGES - Ethanol, Levomenthol, Liquid glucose, Sucrose, Colour Sunset yellow, Colour Quinoline yellow, Flavour Spearmint, Flavour Peppermint.

MEDI-KEEL A® HONEY AND LEMON THROAT LOZENGES - Ethanol, Levomenthol, Liquid Glucose, Sucrose, Caramel, Flavour Honey Yucatan, Flavour Lemon Givaudan.

MEDI-KEEL A® BLACKCURRANT THROAT LOZENGES – Ethanol, Levomenthol, Liquid Glucose, Sucrose, Flavour Blackcurrant, Colour Black, Colour Grape.

PHARMACOLOGICAL CLASSIFICATION:

A 16.3 Surface anaesthetics

PHARMACOLOGICAL ACTION:

Benzocaine is a mild local anaesthetic.

Cetylpyridinium chloride is a quaternary pyridinium antiseptic compound. It has antibacterial and antifungal properties.

Some Gram-negative bacteria, especially *Pseudomonas cepacia*, are resistant.

INDICATIONS:

For the symptomatic relief of sore throat.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

Known sensitivity to benzocaine or cetylpyridinium chloride.

Benzocaine is contraindicated in patients with low plasma-cholinesterase concentrations or in those receiving anticholinesterases.

Safety in pregnancy and lactation has not been established.

Not recommended for children under 6 years of age.

DOSAGE AND DIRECTIONS FOR USE:

Dissolve one lozenge slowly in the mouth, every 2 to 3 hours as required.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Benzocaine:

Some patients may become hypersensitive after repeated use.

Severe sore throat or sore throat accompanied by fever or headache or nausea and vomiting, or any sore throat persisting for more than two days, may be serious. In such cases, consult a physician.

Systemic adverse effects may occur with benzocaine, as a result of the absorption of large amounts through mucous membranes or damaged skin or from highly vascular areas. Excitation of the CNS may be manifested by yawning, restlessness, excitement, nervousness, dizziness, tinnitus, nystagmus, blurred vision, nausea and vomiting, muscle twitching, tremors and convulsions. Numbness of the tongue and

perioral region is an early sign of systemic toxicity. Excitation may be transient and followed by depression with drowsiness, respiratory failure and coma. There may be simultaneous effects on the cardiovascular system with myocardial depression and peripheral vasodilation resulting in hypotension and bradycardia, arrhythmias and cardiac arrest may occur.

Idiosyncratic reactions have been reported. Allergic reactions may occur. Benzocaine should be given with caution to patients with epilepsy, impaired cardiac conduction or respiratory function, or with liver damage; patients with myasthenia gravis are particularly susceptible to the effects of local anaesthetics.

Benzocaine is metabolised to paraaminobenzoic acid and can antagonise the action of sulphonamides.

Benzocaine may impair swallowing and increase the risk of aspiration.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage may cause nausea and vomiting. It has depolarising muscle relaxant properties and toxic symptoms include dyspnoea and cyanosis due to paralysis of the respiratory muscles, possibly leading to asphyxia.

Depression of the central nervous system with convulsions, hypotension and coma may occur.

Treatment is symptomatic and supportive

IDENTIFICATION:

MEDI-KEEL A® THROAT LOZENGES: Yellow, oval, translucent, biconvex lozenge with peppermint/spearmint flavour.

MEDI-KEEL A® HONEY AND LEMON THROAT LOZENGES: Honey-yellow, oval, translucent, biconvex lozenge with lemon honey flavour.

MEDI-KEEL A® BLACKCURRANT THROAT LOZENGES: Maroon, oval, translucent, biconvex lozenge with blackcurrant flavour.

PRESENTATION:

Blister pack of 16 lozenges.

STORAGE INSTRUCTIONS:

Store in cool place (at or below 25 °C) protected from light and moisture.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

MEDI-KEEL A® THROAT LOZENGES: T/16.3/223

MEDI-KEEL A® HONEY AND LEMON THROAT LOZENGES: 33/16.3/0496

MEDI-KEEL A® BLACKCURRANT THROAT LOZENGES: 33/16.3/0495

NAME AND BUSINESS ADDRESS OF HOLDER OF THE CERTIFICATE OF REGISTRATION:

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MEDI-KEELA THROATLOZENGES

Namibia: NS1 90/16.3/00138

Botswana: B9323225 S3

MEDI-KEELA HONEYAND LEMON THROAT LOZENGES:

Namibia: NS1 05/16.3/0170

MEDI-KEELABLACKCURRANT THROAT LOZENGES:

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