SCHEDULING STATUS: **S1**

PROPRIETARY NAME (AND DOSAGE FORM):

MEDI-KEEL A® THROAT GARGLE (SOLUTION)

COMPOSITION:

Each 15 ml contains:

Dibucaine hydrochloride	5 mg
Benzocaine	30 mg
Cetylpyridinium chloride	3,713 mg
Benzyl alcohol	60 mg
Alcohol (as preservative)	15,3 % v/v

Disodium edetate (as antioxidant)

Sugar free

List of Excipients:

Colour Sunset Yellow H. 8070, Disodium Edetate, Ethanol (96,5) %, Eucalyptol, Glycerol, Levomenthol, Methyl Salicylate, Oil Peppermint LR 5396, Poloxamer 188, Purified Water and Sodium Chloride

CATEGORY AND CLASS:

A 16.3 Surface anaesthetics

PHARMACOLOGICAL ACTION:

Dibucaine and benzocaine have a mild local anaesthetic action which alleviates sore throat. Cetylpyridinium chloride is a quaternary ammonium compound. In vitro findings show cetylpyridinium

chloride to have a rapid and prolonged bactericidal and fungicidal action. It is germicidal in high dilutions against a wide variety of Gram-positive and Gram-negative bacteria which include haemolytic Streptococci, Staphylococcus aureus, Escherichia coli and Lactobacillus acidophilus. Fungicidal action has been demonstrated against Monilia albicans, the cause of oral thrush.

INDICATIONS:

MEDI-KEEL A THROAT GARGLE is indicated for rapid and temporary relief of pain and discomfort in: sore throats due to colds, throat irritations (and accompanying tickling cough) due to dust, allergy, smoke or excessive use of the voice. **MEDI-KEEL A THROAT GARGLE** is also recommended for minor mouth irritations due to stomatitis, dental procedures and minor surgery of the mouth.

CONTRAINDICATIONS:

MEDI-KEEL A THROAT GARGLE is contraindicated in patients with a history of hypersensitivity to local anaesthetics.

WARNINGS AND SPECIAL PRECAUTIONS:

MEDI-KEEL A THROAT GARGLE should be used with caution in patients with severely traumatized mucosa and sepsis in the region of the proposed application. This preparation must not be administered to persons who are allergic to benzocaine or related substances.

MEDI-KEEL A® may not to be used in children under the age of 2 years.

DOSAGE AND DIRECTIONS FOR USE:

15 to 30 ml (3 to 6 medicine measuresful) every 3 to 4 hours as needed. Depending upon location of the pain, the solution should be swished around the mouth and/or used as a gargle.

Do not swallow.

Do not exceed the recommended dose.

SIDE EFFECTS:

Persons with a high fever, severe sore throat or persistent cough should not use this preparation unless directed by a physician.

MEDI-KEEL A THROAT GARGLE may cause methaemoglobinaemia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

No cases of overdosage have been reported to date. Stomach washout and supportive therapy are advised.

IDENTIFICATION:

Clear, orange/red liquid with characteristic odour.

PRESENTATION:

100 ml and 200 ml bottles.

STORAGE INSTRUCTIONS:

Store in a cool, dark place at or below 25 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

APPLICATION NUMBER:

H/16.3/199

NAME AND ADDRESS OF HOLDER OF THE CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

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