

1. NAME OF THE MEDICINE

MEDI-KEEL A ®THROAT LOZENGES
MEDI-KEEL A® HONEY AND LEMON THROAT LOZENGES
MEDI-KEEL A® BLACKCURRANT THROAT LOZENGES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each lozenge contains:	
Benzocaine	12,0 mg
Cetylpyridinium chloride	1,5 mg

Contains sugar: Sucrose 2,32 g and
Liquid glucose 1,54 g For a full list of
excipients see section 6.1

3. PHARMACEUTICAL FORM

Lozenges.

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.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications

For the symptomatic relief of sore throat.

4.2 Posology and method of administration

Dissolve one lozenge slowly in the mouth, every 2 to 3 hours as required. Consult a doctor if sore throat persists for more than two days.

Not recommended for use in children under 6 years of age (see section 4.4)

4.3 Contraindications

- Known hypersensitivity to benzocaine, cetylpyridinium chloride or to any of the excipients listed under Section 6.1.
- Benzocaine is contraindicated in patients with low plasma-cholinesterase concentrations or in those receiving anticholinesterases.
- Not recommended for children under 6 years of age (see Section 4.4).

- Local anaesthetics should not be used in patients with complete heart block.

4.4 Special warnings and precautions for use

- 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.
- Excitation may be transient and followed by depression with drowsiness, respiratory failure and coma.
- Numbness of the tongue and perioral region is an early sign of systemic toxicity.
- Benzocaine may impair swallowing and increase the risk of aspiration.
- There may be simultaneous effects on the cardiovascular system with myocardial depression and peripheral vasodilation resulting in hypotension and bradycardia, dysrhythmias and cardiac arrest may occur.
- Benzocaine should be given with caution to patients that are elderly, debilitated, children, epilepsy, impaired respiratory function, shock, liver damage; patients with myasthenia gravis are particularly susceptible to the effects of local anaesthetics.
- Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose- galactose mal-absorption or sucrase-isomaltase insufficiency should not take this product.
- Contains sucrose and glucose which may have an effect on the glycaemic control of patients with diabetes mellitus.
- MEDI-KEEL A THROAT LOZENGES contains sunset yellow which may cause allergic reactions.

4.5 Interaction with other medicines and other forms of interaction **Interactions with other medicines**

- *Benzocaine* is metabolised to para-aminobenzoic acid and can antagonise the action of *sulphonamides*.

- The metabolism of *ester-type local anaesthetics* may be inhibited by *anticholinesterases*, increasing the risk of systemic toxicity.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No fertility data available.

4.7 Effects on ability to drive and use machines

MEDI-KEEL A ®THROAT LOZENGES may cause drowsiness or light-headedness followed by sedation. The effects of this product on the ability to drive and use of machines has not yet been established. Patients taking MEDI-KEEL A ®THROAT LOZENGES, should be advised not to drive or use machinery until they know how MEDI-KEEL A ®THROAT LOZENGES affects them.

4.8 Undesirable effects

a. Summary of the safety profile

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.

b. Tabulated list of adverse reactions

The undesirable effects listed are based on the MedDRA system organ classes (SOC) classification system. The frequency groupings listed conform to the following convention: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1\ 000$ to $< 1/100$); rare ($\geq 1/10\ 000$ to $< 1/1\ 000$); very rare ($< 1/10\ 000$) and unknown (cannot be estimated from the available data)

System Organ Class	Frequency	Undesirable effect
Blood and lymphatic system disorders	Unknown	methemoglobinaemia
Immune system disorders	Unknown	allergic reactions
Psychiatric disorders	Unknown	restlessness, excitement, nervousness, drowsiness, paraesthesias, light-headedness followed by sedation
Eye disorders	Unknown	blurred vision
Ear and labyrinth disorders	Unknown	dizziness, tinnitus, nystagmus,

Cardiac disorders	Unknown	myocardial depression, hypotension, bradycardia, dysrhythmias and cardiac arrest
Respiratory, thoracic and mediastinal disorders	Unknown	yawning, respiratory failure
Gastrointestinal disorders	Unknown	nausea and vomiting, numbness of the tongue and perioral region
Musculoskeletal and connective tissue disorders	Unknown	muscle twitching, tremors and convulsions.
General disorders and administration site conditions	Unknown	coma, idiosyncratic reactions

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 the respective NRA.

4.9 Overdose

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. Numbness of the tongue and perioral region, and light-headedness followed by sedation are early signs of systemic toxicity. Excitation may be transient and followed by depression with drowsiness, respiratory failure. Depression of the central nervous system with convulsions, hypotension and coma may occur. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

A. 16.3 Surface anaesthetics

WHO ATCC Code: R02AD Anaesthetics, local

5.1 Pharmacodynamics properties

Cetylpyridinium chloride is a quaternary pyridinium antiseptic with actions and uses similar to those of other cationic surfactants. It is used chiefly as lozenges or solutions for the treatment of minor infections of the mouth and throat.

Benzocaine, a para-aminobenzoic acid ester, is a local anaesthetic used for surface anaesthesia. It is used, often with other medicines for the temporary local relief of pain associated with dental conditions and oropharyngeal disorders.

Local anaesthetics act by preventing the generation and transmission of impulses along nerve fibres and at nerve endings; depolarisation and ion-exchange are inhibited. The effects are reversible.

5.2 Pharmacokinetic properties

Benzocaine has low potency and low systemic toxicity.

Most local anaesthetics are readily absorbed through mucous membranes, and through' damaged skin. Local anaesthetics are weak bases and at tissue pH can diffuse through connective tissue and cellular membranes to reach the nerve fibre where ionisation can occur. Anaesthetics of the ester type are hydrolysed by esterases in the plasma and, to a lesser extent, in the liver.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

<i>Ingredient</i>	<i>Medi-Keel A Throat Lozenges</i>	<i>Medi-Keel A Honey & Lemon Throat Lozenges</i>	<i>Medi-Keel A Blackcurrant Throat Lozenges</i>
Caramel [E150]	-	X	- -
Colour Black	-	-	X
Colour Grape	-	-	X
Colour Quinoline yellow powder	X	-	- -
Colour sunset yellow	X	-	- -
Ethanol	X	X	X
Flavour Blackcurrant	-	- -	X
Flavour Honey Yucatan	-	X	- -
Flavour Lemon	-	X	- -
Flavour Peppermint	X	-	- -
Flavour spearmint	X	- -	- -
Levomenthol	X	X	X
Liquid glucose	X	X	X
Purified water**	X	X	X
Sucrose [E955]	X	X	X

6.2 Incompatibilities

No information available.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

2 x Blister pack of 8's consisting of aluminium foil and Triplex clear PVC/PE/PVDC foil, packed in a unit carton.

6.6 Special precautions for disposal

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

1 New Road, Erand
Gardens Midrand,
1685
Customer Care: 0860 ADCOCK /
232625 www.adcock.com

8. REGISTRATION NUMBERS:

MEDI-KEEL A THROAT LOZENGES: 7766/R1

MEDI-KEEL A HONEY AND LEMON THROAT
LOZENGES: 9754

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

07 July 1986, 07/11/2025

10. DATE OF REVISION OF THE TEXT

07/11/2025