

**REGAL PHARMACEUTICALS LIMITED
NAIROBI, KENYA**

**SUMMARY OF PHARMACEUTICAL CHARACTERISTICS
(SmPC)**

**SONATEC MOUTHWASH MENTHOL FRESH (ALCOHOL FREE) -
QUERY RESPONSE**

**REF. NO.: DFAR/HMDAR/078/FDA/2023
RWANDA FOOD AND DRUGS AUTHORITY (RFDA)**

SONATEC MOUTHWASH MENTHOL FRESH (ALCOHOL FREE)

Summary of Product Characteristics

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1. Name of the medicinal product

Sonatec Mouthwash Alcohol free

2. Qualitative and quantitative composition

<u>Active Ingredient</u>	<u>% w/v</u>
Cetyl Pyridinium Chloride BP	0.05

3. Pharmaceutical form

Mouthwash

4. Clinical particulars**4.1 Therapeutic indications**

For the relief of mouth, gums and throat infections.

For use after dental surgery and for daily oral hygiene.

4.2 Posology and method of administration

For adults and children over six years, thoroughly rinse the mouth or gargle with at least 20ml (1 tablespoonful) every six hours.

Do not swallow.

Do not dilute. Product is ready for use.

4.3 Contraindications

Hypersensitivity to any of the ingredients, especially cetyl pyridinium chloride.

4.4 Special warnings and precautions for use

Prolonged use of this preparation could lead to hypersensitivity to cetyl pyridinium.

If symptoms persist consult your doctor.

Keep all medicines out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions known.

4.6 Pregnancy and lactation

The use of this preparation in pregnancy and lactation has not been studied but is unlikely to constitute a hazard.

4.7 Effects on ability to drive and use machines

No adverse effects are anticipated.

4.8 Undesirable effects

Adverse effects are unlikely unless there is sensitivity to the ingredients, especially cetyl pyridinium which may cause nausea or vomiting.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

If accidentally swallowed in large quantities, signs of toxicity will include those associated with alcohol, sorbitol, menthol and cetyl pyridinium ingestion, including euphoria, slurred speech, nausea, vomiting, flatulence, diarrhoea and abdominal pain. Treatment includes stomach aspiration and lavage; supportive therapy should include keeping the patient warm. In children, overdosage could lead to hypoglycaemia, correct with dextrose.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Cetyl pyridinium chloride is a cationic disinfectant with gram, positive and negative activity which has been found to be of value in mouthwashes for treating superficial infections of the mouth and throat.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in the other sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Disodium hydrogen Phosphate Dodecahydrate

Citric Acid anhydrous

Methyl Paraben

Sodium Saccharin

Propylene Glycol

Menthol

Sodium Chloride

Carmosine Colour(E122)

Propyl Paraben

Purified water

6.2 Incompatibilities

None

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C in a dry place, protect from light

7. Registrant

Name and address of holder of a registration.

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Registration number. H2013/CTD811/188

Date of first registration- 15 July 2013

8.Manufacturer

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