

Applicant/PHCR:
Product proprietary name:
Dosage form and strength:
Amendment: PI Safety Update (November 2022)

LHC Pharmaceuticals (Pty) Ltd
SEPTOLETE
Cherry/ Lemon Lozenges

APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

Septolete Cherry Lozenge

Septolete Lemon Lozenge

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains cetylpyridinium chloride equivalent to 1,2 mg of cetylpyridinium.

Contains sugar alcohols:

Glycerol – 3,50 mg/lozenge

Maltitol, Liquid – 476,64 mg/lozenge

Mannitol – 163,88 mg/lozenge

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lozenges

Septolete Cherry Lozenge: Round, biconvex, violet lozenges.

Septolete Lemon Lozenge: Round, biconvex, yellow lozenges.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of sore throat for up to two days.

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4.2 Posology and method of administration

Adults and children over 12 years:

Dissolve one lozenge slowly in the mouth every 4 hours when necessary. Do not exceed 6 lozenges in 24 hours.

4.3 Contraindications

Hypersensitivity to cetylpyridinium chloride or any of the ingredients.

Known sensitivity to Septolete.

Contraindicated in children.

4.4 Special warnings and precautions for use

Severe sore throat or sore throat accompanied by high 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 doctor.

Patients should not take Septolete if they have open wounds in the mouth because cetylpyridinium chloride slows the healing of wounds.

If a patient suffers from chronic cough or hoarseness, a doctor should be consulted.

Use in Children

Insufficient evidence is available to establish safety and efficacy of Septolete in children.

Septolete lozenges contain glycerol, liquid maltitol and mannitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

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4.5 Interaction with other medicines and other forms of interaction

Septolete should not be taken together with milk because milk reduces the antimicrobial efficacy of cetylpyridinium chloride.

The use of surfactant anions (e.g. toothpaste) reduces the efficacy of cetylpyridinium chloride.

No formal interaction studies in humans have been performed.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

There are no formal studies done on the effects of Septolete on the ability to drive or use machinery.

4.8 Undesirable effects

a) Tabulated summary of adverse reactions

System Organ Class	Adverse Events	Frequency
Gastrointestinal disorders	Nausea Vomiting	Frequency unknown
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Frequency unknown
Nervous system disorders	Asphyxia and depression of the central nervous system resulting in convulsions, hypotension and coma.	Frequency unknown

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System Organ Class	Adverse Events	Frequency
Skin and subcutaneous tissue disorders	Angioedema	Frequency unknown
	Hypersensitivity reaction	Less frequent

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 asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

Symptoms

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.

Management

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A.16.4 Naso-pharyngeal and Bucco-pharyngeal Antiseptic.

Pharmacotherapeutic group: Throat preparations, antiseptics. ATC code: R02AA06.

Cetylpyridinium chloride is a quaternary ammonium compound which has bactericidal and fungicidal activity.

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5.3 Preclinical safety

Not applicable.

6. PHARMACEUTICALS PARTICULARS

6.1 List of excipients

Septolete lemon flavour lozenges:

Capol 600 pharma

Castor oil

Colour titanium dioxide (E171)

Color yellow (E 100)

Flavour citron

Flavour limette

Flavour orange oil

Glycerol

Lemon oil

Levomenthol

Magnesium stearate

Maltitol

Mannitol

Povidone K25

Silica colloidal anhydrous.

Capol 600 pharma is composed of:

White Beeswax (Ph.Eur.)

Carnauba wax (Ph.Eur.)

Shellac

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Septolete cherry flavour lozenges:

Capol 600 pharma

Castor oil

Colour titanium dioxide (E171)

Color violet (E 120)

Flavour wild cherry

Glycerol

Lemon oil

Levomenthol

Magnesium stearate

Maltitol

Mannitol

Povidone K25

Silica colloidal anhydrous.

Capol 600 pharma is composed of:

White Beeswax (Ph.Eur.)

Carnauba wax (Ph.Eur.)

Shellac

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

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6.4 Special precautions for storage

Store at or below 25 °C in a dry place. Protect from light and moisture. Keep lozenges in the original container at all times.

6.5 Nature and contents of container

Carton containing 2 PVC/PVDC blister packs of 9 lozenges with a package insert.

The blister pack is made up of a transparent thermoforming PVC/PVD and aluminum foil.

6.6 Special precautions for disposal and other handling

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LHC Pharmaceuticals (Pty) Ltd

N4 Gateway Industrial Park

553 Willow Park Manor

33 Ghaap Street

Pretoria

0184

8. REGISTRATION NUMBER

Septolete Cherry Lozenges – 45/16.4/0808

Septolete Lemon Lozenges – 45/16.4/0809

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09 June 2016

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10. DATE OF REVISION OF THE TEXT

20 December 2022