Poduct Name: SEPTOLETE PLUS

Dosage form: Lozenges

Strength: Benzydamine Hydrochloride 3 mg and Cetylpyridinium Chloride 1 mg

Date of Approval: 04 August 2026

APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

SEPTOLETE PLUS 3 mg/1 mg lozenges

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 3 mg benzydamine hydrochloride and 1 mg cetylpyridinium chloride.

Excipients with known effect:

Contains sugar:

- Isomalt (E953): 2471.285 mg/lozenge

Contains sweetener:

- Sucralose (E955): 3.5 mg/lozenge

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lozenge

Round lozenges with beveled edges and rough surface from light blue to blue colour. Allowed white patches, uneven coloring, the presence of air bubbles in the “hard candy” mass and small jagged edges.

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4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic relief of minor infections and painful conditions of the mouth and throat.

4.2 Posology and method of administration

SEPTOLETE PLUS should not be chewed. They should be slowly dissolved in the mouth. One lozenge should be sucked slowly every one to two hours as required up to a maximum of 12 lozenges per day. Uninterrupted treatment should not exceed seven days.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
Children under 6 years of age because the pharmaceutical form is not suitable for this age group.

4.4 Special warnings and precautions for use

SEPTOLETE PLUS should not be used for more than 7 days. If there are no noticeable results after 3 days, a medical practitioner should be consulted.
The use of topical preparations, especially over a long period of time, may lead to sensitisation, in which case treatment must be suspended and a suitable therapy instituted.
SEPTOLETE PLUS must not be used in combination with anionic compounds, such as those present in toothpastes; therefore, it is not recommended to take the product immediately before or after brushing the teeth.

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SEPTOLETE PLUS contains isomalt (E953). Patients with rare hereditary problems of fructose intolerance should not take this medicine. Excess consumption of products containing Isomalt may have a laxative effect.

If a sore throat is caused or complicated by a bacterial infection, appropriate antibacterial therapy should be considered.

SEPTOLETE PLUS is not recommended in children under 6 years of age.

Benzydamine use is not advisable in patient with hypersensitivity to salicylic acid or other NSAIDs.

Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma. Caution should be exercised in these patients.

4.5 Interaction with other medicines and other forms of interaction

SEPTOLETE PLUS should not be used at the same time as other antiseptics.

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

4.6 Fertility, pregnancy and lactation

The safety of benzydamine hydrochloride has not been established in pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of benzydamine hydrochloride and cetylpyridinium chloride in pregnant women.

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SEPTOLETE PLUS is not recommended during pregnancy.

Breast-feeding

It is unknown whether benzydamine hydrochloride/metabolites are excreted in human milk.

A risk to the newborns/infants cannot be excluded.

4.7 Effects on ability to drive and use machines

SEPTOLETE PLUS has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported reaction is oral numbness. Burning or stinging sensation has been reported. Other local adverse effects include dryness or thirst, tingling, warm feeling in mouth and altered sense of taste.

Tabulated summary of adverse reactions

The following undesirable effects have been observed and reported during treatment with **SEPTOLETE PLUS**:

System organ Class	Frequent	Less Frequent	Frequency Unknown
Immune system disorders			Anaphylactic reaction, Hypersensitivity reaction
Nervous system disorders			Burning mucosa Anaesthesia of the oral mucosa

Respiratory, thoracic and mediastinal disorders		Bronchospasm, laryngospasm	
Gastrointestinal disorders		Irritation of the oral mucosa Burning sensation in the mouth, dry mouth	
Skin and subcutaneous tissue disorders		Urticaria, Photosensitivity, angioedema	

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 SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

Symptoms

Toxic manifestations of benzydamine overdose consist of excitement, convulsions, sweating, ataxia, shivering,nausea and vomiting.

Signs and symptoms of intoxication as a result of the ingestion of significant quantities of cetylpyridinium chloride include nausea, vomiting, dyspnoea, cyanosis, asphyxia following paralysis of the respiratory muscles, depression of the CNS, hypotension and coma. The lethal dose in humans is approximately 1-3 grams.

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Excess consumption of products containing isomalt may have a laxative effect.

Management

Since there is no specific antidote, the treatment of acute overdose is purely symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Antiseptics

Pharmacotherapeutic group: Throat preparations, antiseptics; ATC code: R02AA20.

Mechanism of action

Benzydamine hydrochloride is a molecule with a nonsteroidal chemical structure with anti-inflammatory and analgesic properties. The mechanism of action seems attributable to the inhibition of prostaglandin synthesis and thereby to the reduction of local signs of inflammation (such as pain, redness, swelling, heat and impaired function). Benzydamine hydrochloride also possesses a moderate local anaesthetic effect.

Cetylpyridinium chloride is a cation antiseptic of the quarternary ammonium salts group.

Clinical efficacy and safety

Benzydamine is used predominantly in the treatment of disorders of the oropharyngeal cavity. Cetylpyridinium chloride is active against gram-positive bacteria and less active against gram-negative bacteria, and therefore exerts an optimum antiseptic and germicidal action. It also has antifungal properties.

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5.2 Pharmacokinetic properties

Absorption

The absorption through the mucosa of the mouth and pharynx was demonstrated by the presence of measurable quantities of benzydamine in the human plasma.

Distribution

About 2 hours after the 3 mg lozenge administration, benzydamine peak plasma values of 37.8 ng/ml with an AUC of 367 ng/ml*h were observed. However, these levels are not sufficient to produce pharmacological systemic effects.

When locally applied benzydamine has been shown to accumulate in inflamed tissues where it reaches effective concentrations because of its capacity to penetrate the epithelial lining.

Elimination

The medicine is excreted principally through the urine and, for the most part, in the form of inactive metabolites. The half-life and the systemic clearance are similar in all pharmaceutical forms.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Eucalyptus oil

Levomenthol

Citric acid, anhydrous (E330)

Sucralose (E955)

Isomalt (E953)

Brilliant blue FCF (E133)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store at or below 30 °C.

Store in the original package in order to protect from light.

6.5 Nature and contents of container

Blister (PVC/PE/PVDC//Alu foil): 8 or 16, lozenges, in a box.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LHC Pharmaceuticals (Pty) Ltd

N4 Gate Way Industrial Park

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553 Willow Park Manor

33 Ghaap Street

Pretoria

0184

8. REGISTRATION NUMBER(S)

54/16.4/0838.387

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04 August 2026

10. DATE OF REVISION OF THE TEXT