HCR: LHC Pharmaceuticals (Pty) Ltd

Product Name: Septolete Plus Spray

Dosage form and strength: Oromucosal Spray (Solution), Benzydamine Hydrochloride 1.5 mg/ml and Cetylpyridinium Chloride 5 mg/ml

Date of Approval: 10 September 2024

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SCHEDULING STATUS

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1. NAME OF THE MEDICINE

Septolete Plus Spray

2. QUALITATIVE AND QUANTITAVE COMPOSITION

Each ml contains Benzydamine Hydrochloride 1.5 mg and Cetylpyridinium Chloride 5 mg.

One spray contains 0.1 ml solution containing Benzydamine hydrochloride 0,15 mg and Cetylpyridinium chloride 0,5 mg.

For full list of excipients, see section 6.1

Contains alcohol:

Ethanol (96 %) 26,76 % *w/v*

Contains sweetener:

Saccharin sodium: 0,92 mg/ml

Sugar free

3. PHARMACEUTICAL FORM

Oromucosal spray, solution.

Clear, colourless to yellowish liquid**.**

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Septolete Plus spray is indicated in adults and children over 6 years of age for:

- anti-inflammatory, analgesic and antiseptic treatment of irritations in the throat, mouth and gums,

- in gingivitis, pharyngitis and laryngitis,
- before and after tooth extractions.

4.2 Posology and method of administration

Posology

Adults:

For a single dose, the spray head should be pressed once to twice. This may be repeated every 2 hours, 3-5 times a day.

For optimal effect, it is not recommended to use the product immediately before or after cleaning teeth.

The stated dose should not be exceeded.

Septolete Plus Spray can be used for up to 7 days.

Elderly patients:

The recommended dose is the same as for adults.

Paediatric population:

Children over 12 years of age: For a single dose, the spray head should be pressed once to twice. This may be repeated every 2 hours, 3-5 times a day.

Children from 6 to 12 years of age: For a single dose, the spray head should be pressed once. This may be repeated every 2 hours, 3-5 times a day.

Septolete Plus is contraindicated in children under 6 years of age.

Method of administration

Before the first use of **Septolete Plus** Spray, press the spray several times in order to obtain even delivery. If the spray has not been used for a long period of time (like at least for one week), press the spray head one time in order to obtain even delivery.

Remove the plastic cap before use.

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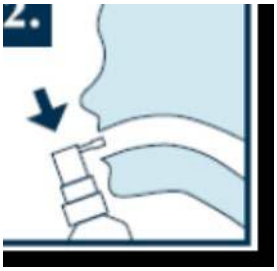
Open your mouth wide, point the spray nozzle towards your throat and press the spray head 1-2 times. Hold your breath while spraying.



After each use, place the plastic cap on the spray head.

When the spray head is pressed once, 0.1 ml of oromucosal spray, solution, which contains 0.15 mg benzydamine hydrochloride and 0.5 mg cetylpyridinium chloride is released.

4.3 Contraindications

Hypersensitivity to benzydamine hydrochloride, cetylpyridinium chloride or to any of the excipients of **Septolete Plus** Spray listed in section 6.1.

Children aged under 6 years since the pharmaceutical form is not appropriate for this age group

4.4 Special warnings and precautions for use

- **Septolete Plus** Spray should not be used for more than 7 days. If there are no noticeable results after 3 days, a doctor 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 instated.

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- **Septolete Plus** Spray must not be used in combination with anionic compounds, such as those present in toothpastes, therefore it is not recommended to use the product immediately before or after cleaning teeth (see section 4.5)
- Direct contact of **Septolete Plus** with eyes should be avoided.
- **Septolete Plus** Spray must not be inhaled.
- **Septolete Plus** Spray contains small amounts of ethanol (alcohol), less than 100 mg per dose.

4.5 Interaction with other medicines and other forms of interaction

Septolete Plus Spray should not be used at the same time as other antiseptics.

Septolete Plus Spray must not be used in combination with anionic compounds, such as those present in toothpastes, therefore it is not recommended to use the product immediately before or after cleaning teeth (see section 4.4)

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of benzydamine hydrochloride and cetylpyridinium chloride in pregnant women. **Septolete Plus** is not recommended during pregnancy.

Breastfeeding

Septolete Plus Spray should not be used in during lactation unless considered essential by the medical doctor.

It is unknown whether benzydamine hydrochloride/metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from

Septolete Plus Spray therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

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4.7 Effects on ability to drive and use machines

Septolete Plus Spray does not influence the ability to drive or use machines.

4.8 Undesirable effects

Tabulated list of adverse reactions

Adverse reactions are tabulated below by System Organ Class (SOC) and frequency. The following convention has been utilized for the classification of undesirable effects:

FREQUENT implies very common (≥1/10) or common (≥ 1/100, <1/10)

LESS FREQUENT implies uncommon (≥1/1000, <1/100), rare (≥1/10 000, <1/1000), very rare (<1/10 000), single or isolated reports.

FREQUENCY UNKNOWN implies it cannot be estimated from available data.

System organ Class	**Frequency**		
	Frequent	**Less Frequent**	**Unknown**
Immune system disorders		Hypersensitivity reactions	
Nervous system disorders			Burning mucosa, Anaesthesia of oral mucosa
Respiratory, thoracic and mediastinal disorders		Bronchospasm	
Gastrointestinal disorders		Oral mucosal irritation, Burning oral sensation	Numbness furry tongue and paraesthesia in the mouth
Skin and subcutaneous tissue disorders		Urticaria, Photosensitivity	
General disorders and administration site conditions			Medicine intolerance, that occurs as burning or irritation at the application site

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 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

Toxic manifestations of benzydamine overdose consist of excitement, convulsions, sweating, ataxia, shivering and vomiting. Since there is no specific antidote, the treatment of acute benzydamine intoxication is purely symptomatic.

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.

Management

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 16.4 Nasopharyngeal and bucco-pharyngeal 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 by this to the reduction of local signs of inflammation (such as pain, redness, swelling, heat and impaired function). Benzydamine is used predominantly in the treatment of disorders of the oropharyngeal cavity.

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Cetylpyridinium chloride is a cation antiseptic of the quarternary ammonium salts group. Cetylpyridinium chloride is active against gram-positive bacteria and less active against gram-negative bacteria, and therefore performs an optimum antiseptic and germicidal action. It also has antifungal properties.

5.2 Pharmacokinetic properties

Absorption

Of the two active substances, cetylpyridinium and benzydamine, only benzydamine is absorbed. Therefore cetylpyridinium does not give rise to pharmacokinetic interactions with benzydamine at a systemic level.

The absorption of benzydamine through the oropharyngeal mucosa is demonstrated by the discovery of detectable quantities of the active substance in the serum, nevertheless insufficient to produce systemic effects.

Elimination

Excretion takes place principally through the urine and, for the most part, in the form of inactive metabolites.

6.PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96 %

Glycerol

Macrogolglycerol hydroxystearate

Saccharin sodium

Peppermint oil

Purified water

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6.2 Incompatibilities

Not applicable

6.3 Shelf Life

36 months unopened.

Once the container is opened, the product should be used within 12 months when stored at temperature below 25 °C.

6.4 Special precautions for storage

Store at or below 25 ºC.

For storage conditions after first opening of the medicine, see section 6.3

6.5 Nature of contents of container

Plastic spray container (HDPE) with white spray pump with actuator and blue plastic (PP) cap: 30 ml of oromucosal spray, solution, in a box. 30 ml of oromucosal spray, solution is sufficient for 250 sprays.

6.6 Special precautions for disposal and other handling

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

LHC Pharmaceuticals (Pty) Ltd

N4 Gate Way Industrial Park

553 Willow Park Manor

33 Ghaap Street

Pretoria

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8. REGISTRATION NUMBER (S)

56/16.4/0528.527

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 September 2024

10 DATE OF REVISION OF THE TEXT