

**HCR:** LHC Pharmaceuticals (Pty) Ltd

**Product Name:** **Septotele Plus** Spray

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

**Date:** 10 September 2024

## **APPROVED PATIENT INFORMATION LEAFLET**

### **SCHEDULING STATUS**

**S1**

### **PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM**

**Septotele Plus** 1.5 mg/ml and 5 mg/ml Oromucosal Spray, Solution

Active Substances:

Benzydamine hydrochloride and Cetylpyridinium chloride

Contains alcohol:

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

Contains sweetener:

Saccharin sodium 0,92 mg/ml

**Read all of this leaflet carefully because it contains important information for you**

**Septotele Plus** Spray is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use **Septotele Plus** Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **Septotele Plus** Spray with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

### **What is in this leaflet**

1. What **Septotele Plus** Spray is and what it is used for
2. What you need to know before you use **Septotele Plus** Spray
3. How to use **Septotele Plus** Spray
4. Possible side effects
5. How to store **Septotele Plus** Spray
6. Contents of the pack and other information



**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:** 10 September 2024

### APPROVED PATIENT INFORMATION LEAFLET

#### 1. What Septolete TOTAL Spray is and what it is used for

**Septolete Plus** Spray is a solution with anti-inflammatory, analgesic and antiseptic medicine for local oral use. The spray disinfects the mouth and throat and reduces signs of inflammation of throat such as pain, redness, swelling, heat and impaired function.

**Septolete Plus** Spray is used for anti-inflammatory, analgesic and antiseptic treatment:

- of irritations in the throat, mouth and gums,
- in gingivitis (gum disease), pharyngitis (inflammation of the pharynx, the back of the throat) and laryngitis (inflammation of the larynx, voice box) and
- before and after tooth extractions.

#### 2. What you need to know before you use Septolete Plus Spray

##### Do not use Septolete Plus Spray

- If you are hypersensitive (allergic) to benzydamine hydrochloride, cetylpyridinium chloride or any of the other ingredients of **Septolete Plus** Spray (listed in section 6).
- This medicine should not be used in children aged under 6 years since this pharmaceutical form is not suitable for this age group.

#### Warnings and precautions

Take special care with **Septolete Plus** Spray:

- Do not use **Septolete Plus** Spray for more than 7 days. If the symptoms worsen or do not relieve after 3 days, or if other symptoms, such as fever occur, consult a doctor.
- The use of topical preparations, especially over a long period of time, may lead to sensitisation in which case treatment must be discontinued and consult your doctor to start a suitable therapy.
- **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.



**HCR:** LHC Pharmaceuticals (Pty) Ltd

**Product Name:** **Septotele Plus** Spray

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

**Date:** 10 September 2024

#### **APPROVED PATIENT INFORMATION LEAFLET**

- Direct contact of **Septotele Plus** Spray, solution with eyes should be avoided.
- The product must not be inhaled.

#### **Children and adolescents**

- **Septotele Plus** Spray must not be used in children under 6 years of age, since it is not suitable for use in this age group.

#### **Other medicines and Septotele Plus Spray**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- Do not use other oral antiseptics when using **Septotele Plus** Spray.
- **Septotele Plus** Spray must not be used in combination with anionic compounds, such as those present in toothpastes.

#### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

**Septotele Plus** Spray is not recommended during pregnancy.

You should discuss breastfeeding with your doctor, and he/she will decide whether you should stop breast-feeding or stop the therapy with **Septotele Plus** Spray.

#### **Driving and using machines**

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

**Septotele Plus** Spray contains ethanol

**Septotele Plus** contains small amounts of ethanol (alcohol), less than 100 mg per dose.



**HCR:** LHC Pharmaceuticals (Pty) Ltd

**Product Name:** Septotele Plus Spray

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

**Date:** 10 September 2024

### APPROVED PATIENT INFORMATION LEAFLET

#### 3. How to use Septotele Plus Spray

Do not share medicines prescribed for you with any other person.

Always use **Septotele Plus** Spray exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

##### **Adults:**

For a single dose, press the spray head **once to twice**. You may repeat this every 2 hours, 3 – 5 times daily.

##### **Use in Children**

*Children over 12 years of age:*

For a single dose, press the spray head **once to twice**. You may repeat this every 2 hours, 3 – 5 times daily.

*Children from 6 to 12 years of age:*

For a single dose, press the spray head **once**. You may repeat this every 2 hours, 3 - 5 times daily.

**Septotele Plus** Spray should not be used in children aged under 6 years.

##### **Do not exceed stated dose.**

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

##### **Method of administration**

Before the first use of **Septotele Plus** Spray, press the spray head 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.

**HCR:** LHC Pharmaceuticals (Pty) Ltd

**Product Name:** Septolete Plus Spray

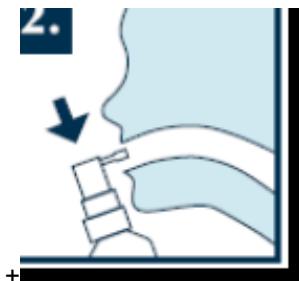
**Dosage form and strength:** Oromucosal Spray(Solution), Benzydamine Hydrochloride 1.5 mg/ml and Cetylpyridinium Chloride 5 mg/ml

**Date:** 10 September 2024

#### APPROVED PATIENT INFORMATION LEAFLET



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



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

#### Duration of treatment

Do not use this medicine for more than 7 days. If the symptoms worsen or do not relieve after 3 days, or if other symptoms, such as fever, occur, consult a doctor. Consult your doctor if the condition is recurrent or if you notice any recent changes in its characteristics.

#### If you use more Septolete Plus Spray than you should

In the event of an over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

#### You may experience the following:

- Convulsions (a sudden, violent, irregular movement of the body)
- Sweating
- Ataxia (the loss of full control of bodily movements)
- Shivering

**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:** 10 September 2024

#### **APPROVED PATIENT INFORMATION LEAFLET**

- Nausea
- Vomiting
- Dyspnoea (difficult or laboured breathing)
- Cyanosis (a bluish discoloration of the skin due to poor circulation)
- Asphyxia (breathing impairment that occurs when there is insufficient oxygen in the body) following paralysis of the respiratory muscles
- Depression of the CNS
- Hypotension and
- Coma

#### **Management of over dosage:**

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

#### **If you forget to use Septolete Plus Spray**

Do not use a double dose to make up for forgotten individual doses.

Use the next dose as previously instructed.

#### **4. Possible side effects**

**Septolete Plus** Spray can have side effects.

Not all side effects reported for **Septolete Plus** Spray are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **Septolete Plus** Spray, please consult your healthcare provider for advice.

If any of the following happen, stop using **Septolete Plus** Spray and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions including swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Skin rash, itchiness, blistering, redness and ulceration of the skin.



**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:** 10 September 2024

#### **APPROVED PATIENT INFORMATION LEAFLET**

- Sensitivity to light

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **Septolete Plus** Spray. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Numbness in the mouth
- Increased breathing
- Stomach cramps or abdominal pain.
- Wheezing, coughing or chest tightness
- Watery red or swollen eyes
- Nasal congestion, runny nose or sneezing
- Fainting
- Tiredness

These are all serious side effects. You may need urgent medical attention.

**Tell your doctor if you notice any of the following:**

##### *Less Frequent*

- hypersensitivity reaction
- hives (urticarial), increase in the reactivity of the skin to sunlight (photosensitivity)
- sudden, uncontrolled narrowing of airways in the lungs (bronchospasm)
- Local irritation in the oral cavity, mild sensation of burning in the oral cavity

##### *Frequency unknown:*

- Burning of the oral mucosa, loss of sensation (anaesthesia) of the oral mucosa.
- Mild and temporary burning at the application site

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

**Reporting of side effects:**



**HCR:** LHC Pharmaceuticals (Pty) Ltd

**Product Name:** Septotele Plus Spray

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

**Date:** 10 September 2024

#### **APPROVED PATIENT INFORMATION LEAFLET**

If you get any side effects, talk to your doctor or pharmacist, or nurse. You can also report side effects 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>.

By reporting side effects, you can help provide more information on the safety of **Septotele Plus** Spray

#### **5. How to Store Septotele Plus Spray**

Store all medicines out of reach of children.

Store at or below 25 °C.

After first opening of the container, the product should be used within 12 months when stored at a temperature below 25 °C.

Do not use the spray after the expiry date shown on the container or box

Do not store in a bathroom.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

#### **6. Contents of the pack and other information**

##### **What Septotele Plus Spray contains**

The active substances are benzydamine hydrochloride and cetylpyridinium chloride.

Each spray contains 0.1 ml solution, containing:

Benzydamine hydrochloride    0,15 mg

Cetylpyridinium chloride        0,50 mg

The other ingredients are:

Ethanol 96 %

Glycerol

Macrogolglycerol hydroxystearate

Saccharin sodium



**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:** 10 September 2024

#### **APPROVED PATIENT INFORMATION LEAFLET**

Peppermint oil

Purified water

#### **What Septolete Plus Spray looks like and contents of the pack**

Clear solution, colourless to yellowish liquid, in a plastic spray container with white spray pump with actuator and blue plastic cap: 30 ml of solution, in a box. 30 ml of, solution is sufficient for 250 sprays.

#### **Holder of Certificate of Registration**

LHC Pharmaceuticals (Pty) Ltd

N4 Gate Way Industrial Park

553 Willow Park Manor

33 Ghaap Street

Pretoria

0184

#### **This leaflet was last revised in**

10 September 2024

#### **Registration Number**

56/16.4/0528.527

#### **Access to the corresponding professional information.**

Corresponding PI can be accessed on the following link:

<http://www.lhcpharma.com/professional-information>

