APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

SEPTOLETE PLUS 3mg/1mg lozenges

Active Substances: Benzydamine Hydrochloride and Cetylpyridinium Chloride

Contains Sugar: Isomalt (E953): 2471.285 mg/lozenge

Contains Sweetener: Sucralose (E955) 3.5 mg/lozenge

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

SEPTOLETE PLUS is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use **SEPTOLETE PLUS** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **SEPTOLETE PLUS** 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 3 days.

What is in this leaflet you

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1. What SEPTOLETE PLUS is and what it is used for

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

2. What you need to know before you take SEPTOLETE PLUS

Do not take SEPTOLETE PLUS:

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

Warnings and precautions

Take special care with **SEPTOLETE PLUS**:

- Do not use **SEPTOLETE PLUS** 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 such case treatment must be discontinued.
- **SEPTOLETE PLUS** 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.

Children and adolescents

- **SEPTOLETE PLUS** must not be used in children under 6 years of age, since the lozenge is not suitable for use in this age group.

Other medicines and SEPTOLETE PLUS

Always tell your healthcare provider doctor if you are taking any other medicines (These includes all

complementary or traditional medicines).

Do not use other antiseptics when taking **SEPTOLETE PLUS**.

SEPTOLETE PLUS with food, drink and alcohol

Do not take **SEPTOLETE PLUS** together with milk because milk reduces their efficacy.

Do not take **SEPTOLETE PLUS** before or during meals. Do not eat or drink for at least one hour after taking **SEPTOLETE PLUS**.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor or pharmacist for advice before taking this medicine.

SEPTOLETE PLUS 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 **SEPTOLETE PLUS**.

Driving and using machines

SEPTOLETE PLUS does not influence the ability to drive or use machines.

It is not always possible to predict to what extent **SEPTOLETE PLUS** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **SEPTOLETE PLUS** affects you.

SEPTOLETE PLUS contains Isomalt (E953)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take SEPTOLETE PLUS

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

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Always take **SEPTOLETE PLUS** exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is: One lozenge every one to two hours.

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.

Children less than 6 years of age

SEPTOLETE PLUS must not be used in children aged less than 6 years.

Do not exceed the stated dose.

Do not take **SEPTOLETE PLUS** immediately before or during meals. Do not eat or drink for at least one hour after taking the medicine.

For optimal effect, it is not recommended to take **SEPTOLETE PLUS** immediately before or after cleaning teeth.

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 take more SEPTOLETE PLUS than you should

In the event of over dosage, consult your doctor or pharmacist. If neither available contact the nearest hospital or poisonous center.

Symptoms:

Over dosage of benzydamine may results in seizures, excitement, sweating, shaky movements, shivering and vomiting

Over dosage of cetylpyridinium chloride may results in nausea, vomiting, difficult breathing, bluish discoloration of skin, suffocation, hypotension and coma. Over dosage of approximately 1 – 3 mg can cause death in human.

If you forget to take SEPTOLETE PLUS

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

4. Possible side effects

SEPTOLETE PLUS can have side effects.

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

<u>If any of the following happens, stop taking **SEPTOLETE PLUS** and tell your doctor immediately or go to the casualty department at your nearest hospital:</u>

- Hypersensitivity reaction which includes swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Hives (urticarial), increase in the reactivity of the skin to sunlight (photosensitivity),
- Sudden, uncontrolled narrowing of airways in lungs (bronchospasm).

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

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

- Local irritation in the oral cavity, mild sensation of burning in the oral cavity.

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

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Tell your doctor if you notice any of the following:

- Burning of the oral mucosa, loss of sensation (anaesthesia) of the oral mucosa.

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

Reporting of side effects

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.

5. How to store SEPTOLETE PLUS

Store all medicine out of reach of children.

Store at or below 30 °C.

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

Do not use after the expiry date stated on the label/ cartoon/ bottle. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose unused medicine in drains or sewage systems (e.g. toilets).

6. Contents of the pack and other information

What SEPTOLETE PLUS contains:

- The active substances are benzydamine hydrochloride and cetylpyridinium chloride. Each lozenge contains 3 mg benzydamine hydrochloride and 1 mg cetylpyridinium chloride.
- The other ingredients are:

  Eucalyptus oil

  Levomenthol

  Citric acid (E330)

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Sucralose (E955)

Isomalt (E953)

Brilliant blue FCF (E133)

What SEPTOLETE PLUS looks like and contents of the pack

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.

SEPTOLETE PLUS are available in boxes of 8 or 16 lozenges in blisters**.**

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Corresponding PI can be accessed on the following link: http://www.lhcpharma.com/professional-information.