

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

LHC Pharmaceuticals (Pty) Ltd
SEPTOLETE
Cherry/ Lemon Lozenges

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

Septolete Cherry 1,2 mg Throat Lozenge

Septolete Lemon 1,2 mg Throat Lozenge

Cetylpyridium chloride

Contains sugar alcohols:

Glycerol – 3,50 mg/lozenge

Maltitol, Liquid – 476,64 mg/lozenge

Mannitol – 163,88 mg/lozenge

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

Septolete is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Septolete carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Septolete 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 2 days.

What is in this leaflet

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

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

LHC Pharmaceuticals (Pty) Ltd
SEPTOLETE
Cherry/ Lemon Lozenges

APPROVED PATIENT INFORMATION LEAFLET

1. What Septolete is and what it is used for

Septolete lozenges exert local antimicrobial activity. They contain the antiseptic cetylpyridinium chloride, which destroys a number of bacteria and fungi. The lozenges disinfect the mouth and throat and thus relieve pain and the feeling of discomfort associated with inflammation of the mouth and throat.

Septolete is used for the symptomatic relief of sore throat for up to two days.

2. What you need to know before you take Septolete lozenges

You should NOT take Septolete lozenges:

- If you are allergic (hypersensitive) to cetylpyridinium chloride or any of the other ingredients of Septolete (listed in section 6).
- Septolete should not be taken by children

Warnings and precautions

Take special care with Septolete Lozenges:

- If you develop severe 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. If any of the symptoms occur, discontinue treatment and consult your doctor or pharmacist.
- If you have open wounds in the mouth (e.g. after tooth extraction, surgical removal of the tonsils) because cetylpyridinium chloride slows the healing of wounds.
- If you have chronic cough and hoarseness, you should consult your doctor.

Children

Septolete lozenges are not recommended in children

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

LHC Pharmaceuticals (Pty) Ltd
SEPTOLETE
Cherry/ Lemon Lozenges

APPROVED PATIENT INFORMATION LEAFLET

Other medicines and Septolete Lozenges

No formal studies have been done on taking Septolete with other medicines.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Septolete with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

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

Septolete with food and drink

Avoiding taking Septolete at the same time with food.

Do not take Septolete together with milk because milk reduces their efficacy.

Pregnancy breast-feeding and fertility

Safety in pregnancy and breast-feeding has not been established.

If you are pregnant or breast-feeding, 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 taking this medicine.

Driving and using machines

No formal studies have been done on the effect of Septolete on driving and operating machinery.

Septolete lozenges contains glycerol, maltitol and mannitol

The lozenges contain glycerol, maltitol and mannitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Septolete.

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

LHC Pharmaceuticals (Pty) Ltd
SEPTOLETE
Cherry/ Lemon Lozenges

APPROVED PATIENT INFORMATION LEAFLET

3. How to take Septolete lozenges

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

Always take Septolete exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose in 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.

If you take more Septolete Lozenges than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take Septolete Lozenges

If you miss a dose, take the next dose as soon as possible, but do not take a double dose to make up for a forgotten individual doses. If you need help in planning the best times to take your medicine, ask your doctor or pharmacist.

4. Possible side effects

Septolete can have side effects.

Not all side-effects reported for Septolete are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Septolete, please consult your doctor, pharmacist or other health care professionals for advice.

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

LHC Pharmaceuticals (Pty) Ltd
SEPTOLETE
Cherry/ Lemon Lozenges

APPROVED PATIENT INFORMATION LEAFLET

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

- Swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Difficulty in breathing with possible suffocation.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Septolete. You may need urgent medical attention or hospitalization. All of these very serious side effects usually occur less frequently.

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

- Fever
- Severe sore throat accompanied by high fever or headache or nausea and vomiting,
- Any sore throat persisting for more than two days
- Slowness or low response of the nervous system.

These are serious side effects. You may need urgent medical attention. Serious side effects usually occur less frequently.

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

LHC Pharmaceuticals (Pty) Ltd
SEPTOLETE
Cherry/ Lemon Lozenges

APPROVED PATIENT INFORMATION LEAFLET

Tell your doctor if you notice any of the following:

Less frequent side effects:

Hypersensitivity reaction

Side effects with unknown frequency:

- Nausea
- Vomiting
- Dyspnoea
- Suffocation resulting in fits, low blood pressure and unconsciousness.
- Angioedema (swelling underneath the skin)

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

Reporting of side effects

If you get 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 Septolete.

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

LHC Pharmaceuticals (Pty) Ltd
SEPTOLETE
Cherry/ Lemon Lozenges

APPROVED PATIENT INFORMATION LEAFLET

5. How to store Septolete Lozenges

Store all medicines out of reach of children.

Store your lozenges at or below 25 °C in a dry place

Keep the lozenges in the original container at all times.

Protect your lozenges from light and moisture.

Do not take this medicine after the expiry date which is clearly marked on the outside of the box.

If your doctor decides to stop your treatment, return any tablets left over to the pharmacist. Only keep them if your doctor tells you to.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Septolete contains

The active substance is: Cetylpyridium chloride equivalent to 1,2 mg of cetylpyridinium.

The other ingredients are:

Septolete lemon flavour lozenges: Capol 600 pharma, castor oil, colour titanium dioxide (E171), color yellow (E 100), ethanol, flavour citron, flavour limette, flavour orange oil, glycerol, lemon oil, levomenthol, magnesium stearate, maltitol, mannitol, povidone K25, purified water and silica colloidal anhydrous.

Septolete cherry flavour lozenges: Capol 600 pharma, castor oil, colour titanium dioxide (E171), color violet (E 120), ethanol, flavour wild cherry, glycerol, lemon oil, levomenthol, magnesium stearate, maltitol, mannitol, povidone K25, purified water and silica colloidal anhydrous.

Contains sugar alcohols: Glycerol 3,50 mg, maltitol, liquid 476,64 mg and mannitol 163,88 mg.

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

LHC Pharmaceuticals (Pty) Ltd
SEPTOLETE
Cherry/ Lemon Lozenges

APPROVED PATIENT INFORMATION LEAFLET

What Septolete Lozenges looks like and contents of the pack

Septolete Cherry Lozenge: Round, biconvex, violet lozenges.

Septolete Lemon Lozenge: Round, biconvex, yellow lozenges.

The lozenges are packed in a carton containing 2 PVC/PVDC blister packs of 9 lozenge tablets with a package insert.

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

Holder of Certificate of Registration

LHC Pharmaceuticals (Pty) Ltd

N4 Gateway Industrial Park

553 Willow Park Manor

33 Ghaap Street

Pretoria

0184

This leaflet was last revised in

20 December 2022

Registration Number

Septolete Cherry Lozenges – 45/16.4/0808

Septolete Lemon Lozenges – 45/16.4/0809

Access to the corresponding Professional Information

The PI will be included in the medicine package