

1.3.1	Cetylpyridinium chloride
SPC, Labeling and Package Leaflet	AM

## 1. NAME OF THE MEDICINAL PRODUCT

Septolete Neo Cherry lozenges 1.2 mg  
Septolete Neo Apple lozenges 1.2 mg  
Septolete Neo Lemon lozenges 1.2 mg

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 1.2 mg cetylpyridinium chloride.  
For excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Lozenges.  
Septolete Neo Cherry: violet, round, slightly biconvex lozenges.  
Septolete Neo Apple: green, round, slightly biconvex lozenges.  
Septolete Neo Lemon: yellow, round, slightly biconvex lozenges.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Septolete Neo lozenges are recommended in infectious-inflammatory diseases of the mouth and throat:

- pharyngitis, laryngitis, beginning of angina,
- inflammation of the gums and oral mucous membrane (gingivitis, stomatitis).

### 4.2. Posology and method of administration

The recommended dosage for adults and children over 12 years of age is up to 8 lozenges a day. Dissolve 1 lozenge in the mouth every 2 to 3 hours.

For children over 4 years of age, up to 4 lozenges a day are recommended while for children from 10 to 12 years of age, up to 6 lozenges a day. Dissolve 1 lozenge in the mouth every 3 to 4 hours.

The lozenges should not be taken immediately before or during meals.

### 4.3 Contraindications

Hypersensitivity to cetylpyridinium chloride or to any of the excipients.  
Children under 4 years of age.

### 4.4 Special warnings and special precautions for use

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The lozenges should not be taken in open wounds in the mouth because cetylpyridinium chloride slows the healing of wounds.

In severe infections accompanied by high fever, headache and vomiting, a physician should be consulted, especially if the condition does not improve in three days.

Diabetic patients should bear in mind that each lozenge contains around 1 g of maltitol. For the metabolism of maltitol, insulin is required but because of slow hydrolysis and absorption in the gastrointestinal tract, the glycemic index is low. The energy value of maltitol (10 kJ/g or 2.4 kcal/g) is also considerably lower than that of sucrose.

It is not recommended to take higher doses than the prescribed ones.

#### ***Special warnings about the excipients***

The lozenges contain natural colours therefore their colour may fade in the course of time if they are kept in a bright place.

The lozenges contain polyols (maltitol, mannitol), which may cause diarrhea at large doses. Large doses of glycerol may cause headache and gastrointestinal disturbances.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

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

#### **4.6 Pregnancy and lactation**

There are no clinical data on the use of cetylpyridinium chloride during pregnancy. Septotele Neo should be prescribed to pregnant women and nursing mothers with caution. They are not recommended for self-medication during pregnancy and lactation.

#### **4.7 Effect on ability to drive and use machines**

The lozenges have not been reported to affect the ability to drive and use machines.

#### **4.8 Undesirable effects**

The undesirable effects that may occur during treatment with cetylpyridinium chloride are listed by frequency, using the following classification:

- very common: >1/10,
- common: >1/100, <1/10,
- uncommon: >1/1000, <1/100,
- rare: >1/10 000, <1/1000,
- very rare: <1/10 000.

Rare: gastrointestinal disturbances, such as nausea and diarrhoea, resulted especially from the use of higher doses than the prescribed ones. High doses of polyols may cause diarrhoea, especially in children.

Very rare: allergic reactions.

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In case of these side effects, the treatment should be discontinued.

## 4.9 Overdose

Due to the low concentration of the active substance in the lozenges, overdosing is almost impossible. Use of higher doses than the recommended ones may cause gastrointestinal disturbances, such as nausea, vomiting and diarrhoea. In that case, patient should stop taking the medicine and consult a doctor.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: throat preparations, antiseptics, ATC code: R02AA06.

Cetylpyridinium chloride is an antiseptic from the group of quaternary ammonium compounds with antimicrobial, antifungal and virucidal activity.

### 5.2 Pharmacokinetic properties

There are no literature data on the pharmacokinetics of cetylpyridinium chloride itself. The most data on the pharmacokinetics of quaternary ammonium compounds were obtained from animal trials. It is generally known that quaternary ammonium compounds are poorly absorbed, i.e. only from 10% to 20%, and the unabsorbed portion is excreted unchanged in the feces.

### 5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

In general, quaternary ammonium compounds are non-toxic and non-irritating to the skin and mucous membranes at the concentrations used for achieving the antiseptic effect.

The oral LD<sub>50</sub> values for cetylpyridinium chloride range from 192 to 538 mg/kg in rats and from 108 to 195 mg/kg in mice. Long-term toxicity studies in rabbits demonstrated no gross pathological changes that could be attributed to cetylpyridinium chloride.

No skeletal deformities were observed in rats in Segment I and Segment III of studies, nor in the perinatal and postnatal period of development. There were also no changes in fertility.

The available literature does not contain any data on the *in vitro* and *in vivo* mutagenic potential of cetylpyridinium chloride.

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## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

Liquid maltitol, maltitol, mannitol, levomenthol, lemon essential oil, glycerol, virgin castor oil, colloidal anhydrous silica, magnesium stearate, povidone, pharmaceutical waxes (bee wax, carnauba wax, shellac), titanium dioxide (E171).

Additional excipients in Septolete Neo Cherry: wild cherry flavour, natural red colour (carminic acid (E120), purified water, potassium hydroxide, citric acid).

Additional excipients in Septolete Neo Apple: apple flavour, natural green colour (copper complexes of chlorophylls and chlorophyllins (E141), purified water, propylene glycol, polysorbate 80, natural yellow colour (curcumin (E100), purified water, acacia (E414), maltodextrin, citric acid (E330), citric esters of fatty acid mono- and diglycerides (E472c), potassium sorbate and sodium benzoate).

Additional excipients in Septolete Neo Lemon: natural lime flavour, lemon flavour, orange oil flavour, natural yellow colour (curcumin (E100), purified water, acacia (E414), maltodextrin citric acid (E330), citric esters of fatty acid mono- and diglycerides (E472c), potassium sorbate and sodium benzoate).

### **6.2. Incompatibilities**

Not applicable.

### **6.3. Shelf life**

3 years.

### **6.4. Special precautions for storage**

Protect from moisture and light. Do not store above 25°C.

### **6.5. Nature and contents of container**

Blister pack (Al foil, PVC/PVDC foil): 18 lozenges (2 blister packs of 9 lozenges) in a box.

### **6.6. Instructions for use and handling**

No special requirements.

## **7. MARKETING AUTHORIZATION HOLDER**

KRKA, d.d. Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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**8. MARKETING AUTHORIZATION NUMBER**

**9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION**

**10. DATE OF REVISION OF THE TEXT**