

# Lemocin Cherry, Lemocin Lemon, Lozenges

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## 1. Composition

### *Active substances*

#### *Each lozenge contains:*

tyrothricin 4 mg, cetrimonium bromide 2 mg, and lidocain 1 mg.

### *Excipients*

*Lemocin Cherry:* sorbitol, guar galactomannan, citric acid, talc, povidone, saccharine sodium, magnesium stearate, cherry flavour (containing cinnamaldehyde, citral, eugenol and geraniol), iron oxide red.

Each lozenge contains 0.7 mg (0.03 mmol) of sodium.

*Lemocin Lemon:* sorbitol, citric acid, talc, lemon flavour (containing butylated hydroxyanisole [E 320], citral, sorbitol [E 420]), guar galactomannan, magnesium stearate, colloidal anhydrous silica, saccharine sodium, quinoline yellow lake, peppermint flavour, spectracol green lake.

Each lozenge contains 0.2 mg (0.01 mmol) of sodium.

## 2. Galenical Form and Quantity of Active Substance per Dosage Unit

*Lemocin Cherry* are pink to red coloured flecked lozenges, , square with bevelled edges on both sides, with cherry flavour.

*Lemocin Lemon* are pale yellowish to dark yellow coloured flecked lozenges, oblong with bevelled edges on both sides, with sweet lime flavour.

## 3. Indications/Uses

For the relief of pain associated with severe sore throat and mouth infections.

This medicine is intended for adults and children over 12 years old.

## 4. Dosage/Administration

The lozenges shall not be chewed or swallowed whole.

The recommended dosage must not be exceeded.

In any case, the lowest effective dose for the shortest possible duration of treatment should be used.

### *Children above the age of 12 and Adults*

For mild to moderate sore throat: one lozenge every 2-3 hours.

For severe sore throat: one lozenge every 1-2 hours.

A daily dose of 12 lozenges should not be exceeded.

### *Method of administration:*

For use in the oral cavity.

While sucking the Lemocin Cherry and/or Lemocin Lemon for a sore throat lozenge, it shall be moved slowly in the mouth and must not be allowed to melt in a cheek pouch.

In case of severe throat infection or sore throat accompanied by high fever, headache, nausea or vomiting, this medicine must not be used without medical advice.

When treating apthae, the lozenge shall be allowed to slowly melt in direct contact with the lesion.

#### *Children and adolescents:*

To date, use and safety of Lemocin Cherry and/or Lemocin Lemon have not yet been studied in children and adolescents.

### **5. Contraindications**

Hypersensitivity to tyrothricin, cetrimonium bromide, lidocaine or any other local anaesthetics of the amide type.

Hypersensitivity to any of the excipients of the product (refer to "*Composition*").

### **6. Special Warnings and Precautions for Use**

Patients should be instructed to consult a physician or pharmacist if they experience a sore throat accompanied by high fever, dizziness and vomiting, with severe discomfort when swallowing, if the symptoms do not improve or persist for longer than 5 to 7 consecutive days. Lemocin Cherry and/or Lemocin Lemon should be used for short-time treatment (5 to 7 days) only.

Lemocin Cherry and/or Lemocin Lemon should not be used while or shortly before drinking or eating. The local anaesthetic effect of lidocaine may cause transient numbness of tongue and throat and thus can impair swallowing.

Lemocin Cherry and/or Lemocin Lemon should be used with caution only in case of any wounds in or injuries to the mucosal lining of mouth and throat.

The products should not be used in combination with anionic substances, such as toothpaste. Anionic substances may reduce the effect of cetrimonium. Therefore, the lozenges shall not be used shortly before or after cleaning the teeth.

Use of antibiotic agents may lead to an overgrowth of non-susceptible pathogens/germs. In general, cases of minor to life-threatening pseudomembranous colitis have been reported after the use of antibiotic agents (in isolated cases also after use of tyrothricin). Therefore, it is important to verify the diagnosis of patients who experience diarrhoea while using or after use of Lemocin Cherry and/or Lemocin Lemon.

In the following cases, treatment with Lemocin Cherry and/or Lemocin Lemon must be stopped and reconsidered:

- if new infections due to bacteria or fungi occur during treatment,
- if persisting or more severe diarrhoea is experienced.

#### *Information on the Excipients*

Lemocin Cherry and Lemocin Lemon contain about 1 g of sorbitol (E 420) per lozenge. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Sorbitol is a source of fructose. Patients with hereditary fructose intolerance (HFI) must not be given this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Lemocin Cherry and Lemocin Lemon contain less than 1 mmol sodium (23 mg) per lozenge, that is to say essentially 'sodium-free'.

Lemocin Cherry contains a fragrance with cinnamaldehyde, citral, eugenol and geraniol. Cinnamaldehyde, citral, eugenol and geraniol may cause allergic reactions. In addition to allergic reactions in sensitized patients, non-sensitized patients may become sensitized.

Lemocin Lemon contains butylated hydroxyanisole (E 320) that may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Lemocin Lemon contains a fragrance with citral. Citral may cause allergic reactions. In addition to allergic reactions in sensitized patients, non-sensitized patients may become sensitized.

### **7. Interactions**

No interaction studies have been conducted.

Tyrothricin: Due to the fact that the active substance will not be absorbed from the gastrointestinal tract, no systemic interactions are expected.

Cetrimonium bromide: Since this active substance is hardly absorbed from the gastrointestinal tract, no systemic interactions are expected. Concomitant application of anionic tensides/surfactants (such as toothpaste) can reduce the effect of cetrimonium bromide.

Lidocaine: Theoretically, lidocaine could react with co-administered medicines (for instance with other anti-arrhythmic agents); however, due to the very small quantities contained in this product, such interactions are not expected.

## **8. Pregnancy / Lactation**

### *Pregnancy*

Lidocaine passes the placental barrier. There are no indications of fetal risks. However, there are no clinical data available from use in pregnant women.

Caution is advised when these products are used during pregnancy. Lemocin Cherry and/or Lemocin Lemon should only be administered during pregnancy if this is clearly indicated.

### *Breast feeding*

Small quantities of lidocaine are excreted in human milk. At therapeutic dosages, the lidocaine active substance levels in human milk will be so low that any risks to the newborn are rated as unlikely.

Due to the fact that no adequate data are available for tyrothricin and cetrimonium bromide, use of Lemocin Cherry and/or Lemocin Lemon during the breast-feeding period is not recommended.

## **9. Effect on the Ability to Drive and Operate Machinery**

Relevant studies have not been conducted.

## **10. Adverse Effects**

Adverse drug reactions are listed below by System Organ Class and frequency. The frequencies are defined according to the following convention: Very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1000$  to  $< 1/100$ ), rare ( $\geq 1/10000$  to  $< 1/1000$ ), very rare ( $< 1/10000$ ). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

### *Immune system disorders*

*Rare:* Systemic hypersensitivity reactions.

### *Gastrointestinal disorders*

Nausea may be experienced when the lidocaine contained in the lozenges is taken at high doses on an empty stomach.

### *Skin and subcutaneous tissue disorders*

*Very rare:* Rash, pruritus.

### *General disorders and administration site conditions*

Frequent and repeated administration for extended periods may cause local irritation. Using tyrothricin on fresh wounds can lead to bleeding.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: <https://sideeffects.health.gov.il>

## **Overdose**

### *Signs and symptoms*

*Tyrothricin:* Upon oral application, tyrothricin will hardly be absorbed and therefore, overdose is considered as clinically unlikely.

*Cetrimonium bromide:* As with all quaternary ammonium compounds, accidental intake of larger amounts of cetrimonium bromide can cause nausea and vomiting. Given the quantities of cetrimonium bromide (quaternary ammonium base) contained in Lemocin Cherry and/or Lemocin Lemon Lozenges, curare-like effects on the nervous system are not expected. Symptomatic treatment is indicated; if necessary, soothing agents should be administered. Induced vomiting and gastric lavage should be avoided. Immediate administration of milk or whipped egg white in water is recommended. Alcohol which favours the absorption should be avoided.

*Lidocaine:* Lidocaine is well absorbed, but also broken down rapidly. However, harmful effects on the central nervous system and the cardiovascular system cannot be ruled out in case of overdosing. If overdose is suspected, the patient shall be monitored carefully. Should intoxication symptoms be developed, the usual symptomatic treatment measures shall be taken.

### *Management*

Management of overdose shall be symptomatic and should comprise supportive measures, depending on the clinical symptoms.

## **11. Properties/Effects**

### *ATC code*

R02AD02

### *Mechanism of action*

Lemocin Cherry and/or Lemocin Lemon is used for local treatment of inflammations in mouth and throat.

Tyrothricin is a typical antibiotic agent having a bacteriostatic effect on gram-positive bacteria. Development of resistance or cross-resistance with other antibiotic agents has not been reported. The possibility of sensitization is low.

The antibacterial action of tyrothricin is complemented by the disinfecting effect of cetrimonium bromide. The latter has a slight surface activity allowing the antibacterial and disinfecting effect to penetrate into the depth of the tissue.

Lidocaine is a local anaesthetic agent of the amide type. Thanks to its local anaesthetic effect, it provides relieve of symptoms like painful swallowing and sore throat experienced with the infection.

### *Pharmacodynamics*

Not applicable.

### *Clinical efficacy*

Not applicable.

## **12. Pharmacokinetics**

### *Absorption*

Tyrothricin is not absorbed.

Cetrimonium bromide is hardly absorbed from the gastrointestinal tract.

Lidocaine is well absorbed from the gastrointestinal tract, via the mucosal lining and injured skin.

#### *Distribution*

Not applicable.

#### *Metabolism*

Following oral administration, absorbed lidocaine is subject to a first-pass metabolism in the liver. Upon oral administration, its bioavailability comes to approximately 35%.

#### *Elimination*

Cetrimonium bromide is excreted unchanged in the faeces and the urine.

The metabolites of lidocaine are excreted in the urine; less than 10% thereof in an unchanged form.

### **13. Preclinical Safety Data**

No product-specific data are available which would be relevant for use.

### **14. Further Information**

#### *Shelf life*

The expiry date is indicated on the printing materials.

#### *Special precautions for storage*

Store below 25°C. Protect from light and moisture.

Store all medicines out of the sight and reach of children.

### **15. Marketing Authorisation Number**

Lemocin Lemon: 117-80-29908-00

Lemocin Cherry: 117-79-29907-00

### **16. Pack sizes**

Lemocin Lemon: 24 or 50 lozenges.

Not all packages size may be marketed.

Lemocin Cherry: 24 lozenges.

### **17. Manufacturer**

Stada Arzneimittel AG

Stadastrasse 2-18, 61118 Bad-Vilbel, Germany

### **18. Marketing Authorisation Holder**

Devries & CO. LTD, 32 Barzel ST., 69710 Tel Aviv

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