

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

**Clearocin Lemon
Clearocin Cherry**

Lozenges

Active ingredients and their quantities:

Each lozenge contains:

lidocaine 1 mg
tyrothricin 4 mg
cetrimonium bromide 2 mg

Inactive ingredients and allergens: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist. Use the medicine according to the instructions provided in the dosage section of this leaflet. Consult your pharmacist if you need further information. Contact your doctor if disease symptoms are worsening or do not improve after 5-7 days.

1. What is this medicine intended for?

Clearocin is a lozenge for relief of severe sore throat and pain associated with oral infections. The medicine is intended for adults and children above the age of 12 years.

Therapeutic group:

Clearocin contains lidocaine (local anaesthetic), tyrothricin (antibiotic) and cetrimonium bromide (antiseptic).

2. Before using this medicine

Do not use this medicine if:

You are sensitive (allergic) to the active ingredients (lidocaine, tyrothricin and cetrimonium bromide) or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine

Before using Clearocin, tell your doctor/pharmacist if:

- You have a sore throat accompanied by fever for several days,
- You have a cut or injury in the mucosal lining of the mouth or throat,
- The symptoms do not improve or persist for longer than 5-7 days,
- You have a sore throat accompanied by high fever, dizziness, vomiting or severe discomfort upon swallowing.

Before using the medicine, inform your doctor/pharmacist if you have any disease or if you have previously experienced allergic reactions.

Do not brush your teeth shortly before or after taking the medicine since toothpaste will reduce the efficacy of the medicine.

Children and adolescents

The medicine is not intended for children below the age of 12 years.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.

Using this medicine and food

Do not use Clearocin shortly before or while eating or drinking, since the local anaesthetic effect of lidocaine may cause temporary numbness of the tongue and throat, and thus can impair swallowing. Refrain from eating as long as this numbness persists.

Pregnancy and breastfeeding

Do not use the medicine during pregnancy or breastfeeding period.

If you are pregnant, breastfeeding or plan to become pregnant, consult your doctor before using any medicines.

Important information about some of this medicine's ingredients

The medicine contains sorbitol. Sorbitol is a source of fructose. If your doctor has told you that you have intolerance to certain sugars or if you have been diagnosed with hereditary fructose intolerance (a rare genetic disorder resulting in inability to break down fructose), consult your doctor before using this medicine.

Sorbitol may cause gastrointestinal discomfort and has a mild laxative effect.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually:

Children above the age of 12 and adults:

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

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

Do not exceed the dose of 12 lozenges in 24 hours.

Do not exceed the recommended dose.

Mode of administration:

While sucking Clearocin Cherry and/or Clearocin Lemon sore throat relief lozenge, move the lozenge slowly in the mouth. Do not allow it to melt inside the cheek!

When treating blisters/aphthae, allow the lozenge to slowly melt directly on the affected site.

Do not chew/break or swallow the lozenge. Suck the lozenge slowly and repeat as required.

If you have accidentally taken a higher dose

Overdose of cetrимonium bromide may cause nausea and vomiting.

Overdose of lidocaine may cause harmful effects on the central nervous system and cardiovascular system.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Clearocin may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop treatment with the medicine and contact your doctor immediately if you experience any of the following side effects:

- **Effects which can indicate an allergic reaction:**
 - Difficulty in breathing or swallowing,
 - Swelling of the face, lips, tongue or throat,
 - Severe skin itching accompanied by red rash or skin bumps.
- Persistent or severe diarrhoea, diarrhoea with blood and mucus, pain in the navel or cramps and/or fever,
- Upon occurrence of a new infection,
- Upon worsening of symptoms.

Additional side effects

Rare side effects (occur in 1-10 in 10,000 users)

Local irritation in the mouth or throat (oral discomfort), mostly when used frequently for a prolonged period.

Using tyrothricin on fresh wounds can lead to bleeding.

Very rare side effects (occur in less than one in 10,000 users)

- Itching, rash
- Nausea, especially when high doses of the medicine are used or when the lozenges are taken on an empty stomach (attributed to lidocaine contained in the lozenges).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C and protect from light and moisture.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Lemon-flavored Clearocin lozenges:

sorbitol, citric acid, talc, lemon flavouring powdered, guar, magnesium stearate, silica colloidal anhydrous, saccharine sodium, quinoline yellow lake, peppermint flavour, spectracol green lake.

Cherry-flavored Clearocin lozenges:

sorbitol, guar, citric acid, talc, povidone, saccharine sodium, magnesium stearate, cherry flavouring, iron oxide pigment red.

What the medicine looks like and contents of the pack:

Clearocin Lemon are dark yellow to lemon-yellow coloured flecked lozenges, oblong with bevelled edges.

Clearocin Cherry are pink-red coloured flecked lozenges, oblong with bevelled edges.
Each pack contains 24 lozenges.

Registration holder's name and address:

Devries & Co. Ltd., 32 Habarzel St., Tel Aviv

Manufacturer's name and address:

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad-Vilbel, Germany

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Clearocin Lemon: 138-27-31730

Clearocin Cherry: 138-29-31729

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