SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Orasept 0,6 mg/1,2 mg/2 mg zuigtabletten

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:

amylmetacresol	0.6 mg
2,4-dichlorobenzyl alcohol	1.2 mg
lidocaine hydrochloride monohydrate	2.0 mg

Excipients with known effect:
Each lozenge contains:

sucrose	1,495 mg
liquid glucose	1,017 mg
sunset yellow (E110)	0.01 mg
citral	
limonene	

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lozenge.
Orasept lozenges are yellow, round, 19 mm diameter, honey and lemon-flavoured lozenges.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For local, short-term, symptomatic treatment of a sore throat in adults and adolescents over 12 years of age.

4.2 Posology and method of administration

Posology
Adults and adolescents over 12 years of age:
1 lozenge every 2 – 3 hours, as needed, up to a maximum of 8 lozenges in a 24-hour period (maximum of 4 lozenges for adolescents).

The lowest effective dose should be used for the shortest possible time.

Paediatric population
The medicinal product is contraindicated in children under 12 years of age (see section 4.3).

Elderly
Adjustment of the dose is not required.

Renal and/or hepatic impairment

There are no data available for use of Orasept in patients with hepatic or renal impairment.

Method of administration
For oromucosal use.
The lozenge should be slowly dissolved in the mouth, it should not be dissolved in the sac of the cheek.

Orasept should not be used less than 30 minutes before or during a meal or a drink because of the risk of aspiration and localized burning from hot food/drink due to the anaesthesia of the throat and tongue (see section 4.4).

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- A history of allergy to local anaesthetics of the amide type.
- In patients who have a history of or are suspected to have methaemoglobinaemia.
- Children under 12 years of age due to the risk of rapid absorption of the anaesthetic and the risk of reflex laryngospasm.

4.4 Special warnings and precautions for use

The patients should follow the indicated dosage: When taken in large amounts or repeatedly, this medicine may impact the nervous system as it passes through the bloodstream, possibly causing convulsions or affecting the heart.

The prolonged use of this medicine for more than 5 days is not recommended, as it may alter the natural microbial balance of the oral cavity.
If symptoms do not improve for more than 2 days, get worse or if other symptoms appear, such as high fever, headache, nausea or vomiting, and skin rash, the clinical condition should be evaluated for bacterial infections (angina, tonsillitis).

Orasept should be administered with caution in acutely ill or frail elderly patients, as they are more sensitive to adverse reactions of this medicinal product.

Asthmatic patients must use this medicinal product under a doctor´s care.

This medicinal product should not be used if there are greater acute wounds in the area of mouth and throat. Orasept may cause numbness of the tongue and may increase the danger of biting trauma. Therefore, care should be taken in eating hot food and drinking hot beverages. The patient should be aware that topical anaesthesia induced by Orasept may impair swallowing and thus enhance the danger of aspiration. For this reason, food should not be ingested directly following use of local anaesthetic preparations in the mouth or throat area.

Excipients with known effect:
Orasept contains 1,495 mg sucrose per lozenge. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
Orasept contains 1,017 mg glucose per lozenge. This should be taken into account in patients with diabetes mellitus. Patients with rare glucose-galactose malabsorption should not take this medicine.
Orasept contains sunset yellow, which may cause allergic reactions.
Orasept contains citral and limonene, which may cause allergic reactions.
Orasept contains sodium. This medicine contains less than 1 mmol sodium (23 mg) per lozenge, that is to say essentially 'sodium free'.

4.5 Interaction with other medicinal products and other forms of interaction

The simultaneous or successive use of other antiseptics is not advised, due to possible interference (antagonism, deactivation).

Although the amount of lidocaine in this medicinal product is low, the following must be considered:

- The toxicity of orally administered lidocaine may be increased with concomitant administration of the following substances:
    - Erythromycin
    - Itraconazole
    - Cimetidine
    - Fluvoxamine
    - Beta-blockers
    - Other antiarrhythmics (e.g. mexiletine, procainamide)

- Beta-adrenergic blocking agents reduce the hepatic blood flow and therefore the speed at which lidocaine is metabolised, resulting in a greater risk of toxicity.

- Cimetidine can inhibit the hepatic metabolism of lidocaine, resulting in a greater risk of toxicity.

- Administration with class III antiarrhythmics, such as mexiletine and procainamide, due to potential pharmacokinetic or pharmacodynamic interactions.

- The isoenzymes CYP1A2 and CYP3A4 of the cytochrome P450 are involved in the formation of MEGX, the pharmacologically active metabolite of lidocaine, and therefore other medications such as fluvoxamine, erythromycin and itraconazole may increase the plasma concentrations of lidocaine.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of Orasept in pregnancy has not been established.
A large amount of data on the local use of lidocaine during pregnancy indicates no increased risk of congenital malformations or foetal/neonatal toxicity of lidocaine. Lidocaine crosses the placenta; however, there is very little absorption as a result of the low dose. Animal studies do not indicate reproductive toxicity (see section 5.3).
There are no data on the use of active substances amylmetacresol and 2,4-dichlorobenzyl alcohol during pregnancy. Orasept is not recommended during pregnancy.

Breastfeeding

Lidocaine and its metabolites are excreted in breast milk but, at the therapeutic doses of Orasept, no effect on the breastfed newborns/infant is anticipated. There are no data on the excretion of amylmetacresol and 2,4- dichlorobenzyl alcohol (or its metabolites) in human milk.
A risk to newborns/infants cannot be excluded. This medicine is therefore not to be used during breast-feeding.

Fertility

There are no data on the effect of lidocaine, amylmetacresol and 2,4-dichlorobenzyl alcohol on male and female fertility.

4.7 Effects on ability to drive and use machines

This medicinal product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

No systemic reactions have been reported up to now and generally only occur after a long-term treatment.
During the period of use, the following adverse reactions have been reported for the combination of active substances in this medicinal product. During treatment of chronic conditions and with long-term use additional side effects may occur.

The adverse reactions associated with the combination of active substances in this medicinal product are described below by system organ class and ranked according to frequency: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1 000 to < 1/100), rare (≥ 1/10 000 to < 1/1 000), very rare (< 1/10 000), not known (cannot be estimated from the available data)

System Organ Class	Frequency	Adverse events
Blood and lymphatic system disorders	Not known	Methaemoglobinaemia
Immune system disorders	Rare	Hypersensitivity reactions[1]
Respiratory, thoracic and mediastinal disorders	Not known	Pharyngeal oedema
Gastrointestinal disorders	Not known	Nausea, oral discomfort[2], swelling of the mouth, dysgeusia
Skin and subcutaneous tissue disorders	Not known	Rash

Description of Selected Adverse Reactions
[1] Hypersensitivity reactions to lidocaine may present in the form of angioedema, urticaria, bronchospasms and hypotension with syncope.
[2] May appear as a burning or itching sensation in the mouth or throat.

Reporting of suspected adverse reactions
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. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Symptoms
Given the low concentrations of active ingredients overdosage is virtually impossible. Overdosage may occur in the event of abnormal use (much higher dosage, mucosal lesions). This manifests itself initially by unusual numbness of the upper respiratory and digestive tracts. Systemic reactions may occur due to the absorption of lidocaine. The most serious effects of lidocaine intoxication are expressed in the central nervous system (insomnia, restlessness, excitement and respiratory depression) and the cardiovascular system (hypotension, cardiac dysrhythmia, cardiac arrest); methemoglobinemia may also occur.

Treatment
Treatment is symptomatic and supportive; medical observation is desirable. Methemoglobinaemia can be treated by immediate intravenous injection of methylene blue (1–4 mg/kg).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Throat preparations, antiseptics.
ATC code: R02AA03.

Through its active substances, this medicinal product combines properties of local antiseptic, bactericide, fungicide and local analgesic.
This medicinal product contains:

- 2,4-Dichlorobenzyl alcohol and amylmetacresol, two antiseptics which act against pathogenic bacterial flora of the oropharyngeal cavity. They belong to the chemical group of alcohols and phenols, respectively.
- Lidocaine, which belongs to the group of local amide anaesthetics, induces rapid relief from pain.

5.2 Pharmacokinetic properties

Absorption and distribution
Lidocaine is absorbed relatively quickly after topical application to the mucous membranes. Based on a study with a lozenge containing 8 mg of lidocaine and assuming linear PK, peak plasma levels obtained after the administration of 2 mg lidocaine lozenges would be around 11 ng/mL, which is far below the levels associated with higher incidence of systemic adverse reactions. Although lidocaine is absorbed in the gastrointestinal tract, only 35% of the oral dose reaches systemic circulation unchanged through a first-pass effect (hepatic portal circulation).

Biotransformation and elimination
Lidocaine is largely metabolised in the liver, whereby any alteration in hepatic function or hepatic blood flow can have a significant effect on pharmacokinetics and dosage requirements. Hepatic metabolism is fast and close to 90% of an administered dose, it is dealkylated to form monoethylglycinexylidide (MEGX) and glycinexylidide (GX). Less than 10% of lidocaine is excreted unchanged by the kidneys. The metabolites are also excreted in the urine.

There are no relevant data on the pharmacokinetics of either 2,4-dichlorobenzyl alcohol or amylmetacresol.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Peppermint oil (contains limonene)
Quinoline yellow (E104)
Sodium saccharin (E954)
Tartaric acid (E334)
Sucrose
Liquid glucose
Sunset yellow (E110)
Lemon essence (contains citral)
Honey flavour (contains 1,2-propanediol and benzeneacetic acid)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Do not store above 30 ºC.

6.5 Nature and contents of container

PVC-PVDC/Aluminium blisters

16, 20, 24, 30 and 36 lozenges
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Dr. Max Pharma s.r.o.
Na Florenci 2116/15
Nové Město
110 00 Praag 1
Tsjechië

8. MARKETING AUTHORISATION NUMBER(S)

RVG 133500

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Datum van eerste verlening van de vergunning: 29 oktober 2025

10. DATE OF REVISION OF THE TEXT

Laatste gedeeltelijke wijziging betreft rubriek 2: 18 februari 2026