

Package leaflet: Information for the patient

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

amylmetacresol/2,4-dichlorobenzyl alcohol/lidocaine hydrochloride monohydrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

What is in this leaflet

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

1. What Orasept is and what it is used for

Orasept contains amylmetacresol and 2,4-dichlorobenzyl alcohol – both antiseptics, and lidocaine hydrochloride – a local anaesthetic which relieves the pain.

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

You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

2. What you need to know before you take Orasept

Do not take Orasept

- If you are allergic to amylmetacresol, 2,4-dichlorobenzyl alcohol, lidocaine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- In children under 12 years of age.
- If you have a history of allergy to local anaesthetics such as bupivacaine and ropivacaine.
- If you have a history of or are suspected to have a blood condition called methaemoglobinaemia (increased concentration of methaemoglobin in blood).

Warnings and precautions

You should consult the use of this medicine with your doctor if:

- the sore throat is accompanied by fever, headache, nausea, vomiting or skin rash.
- your symptoms do not improve or get worse within 2 days of treatment.
- you have greater acute wounds in the area of mouth and throat (Orasept should not be used then).

Susceptible persons may experience strange feeling in the mouth due to the local anaesthetic effect.

The anaesthetics contained in this medicine may cause aspiration (coughing during meals or a choking sensation) while eating. Do not take food directly following the use of this medicine. This medicine 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.

Prolonged use of this medicine (more than 5 days) is not recommended, as it may alter the natural microbial balance of the throat.

Follow the indicated dosage: if taken in large quantities or over the recommended time, this medicine may affect the heart or nervous system and may cause convulsions.

Elderly persons or persons in a weakened condition are more sensitive to possible adverse reactions and should consult their doctor before taking this medicine.

Patients with asthma must take this medicine only under a doctor's care.

Children and adolescents

This medicine must not be used in children under 12 years of age.

Other medicines and Orasept

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The toxicity of oral lidocaine may be increased if it is taken in combination with:

- Antibiotics (drugs for certain bacterial infections), such as erythromycin or antimycotics (medicines against certain fungal infections), such as itraconazole.
- Beta-blockers (used to treat high blood pressure, heart failure, arterial disease or increased eye pressure) or medicines containing cimetidine (used to treat stomach ulcers).
- Medicines such as fluvoxamine (used to treat depression).
- Medicines used to treat heart disorders, such as mexiletine or procainamide.

Orasept with food and drink

Do not take this medicine 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.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The use of this medicinal product is not recommended during pregnancy.

A risk to newborns/infants cannot be excluded. This product is therefore not to be used during breast-feeding.

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

Driving and using machines

Given the properties of the product, it is unlikely that Orasept will have any influence on the ability to drive and use machines.

Orasept contains glucose, sucrose, sunset yellow, citral, limonene and sodium

Orasept contains 1.017 g of glucose and 1.495 g of sucrose per lozenge. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Orasept contains sunset yellow, citral and limonene, which may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per lozenge, that is to say essentially 'sodium free'.

3. How to take Orasept

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

The recommended doses are the following:

Adults and adolescents over 12 years (including elderly)

Dissolve one lozenge slowly in the mouth every 2 to 3 hours, as needed, up to a maximum of 8 lozenges over 24 hours (maximum of 4 lozenges for adolescents).

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

Do not dissolve the lozenge in the sac of the cheek.

Do not use this medicine for more than 5 days. If you are not completely free of the symptoms after that time, consult your doctor.

Use in children and adolescents

The medicine must not be used in children under 12 years of age.

If you take more Orasept than you should

Do not exceed the recommended dosing.

To date, no cases of overdose have been reported.

Symptoms that may occur in case of misuse or overdose: excessive numbness of upper digestive and respiratory tract, insomnia, restlessness, excitement, difficulty breathing, low blood pressure, irregular heartbeat. Increased concentration of methaemoglobin in blood may also occur.

If you take too much Orasept, immediately consult your doctor or pharmacist.

Take this leaflet with you as it will ensure that the appropriate treatment is given as soon as possible.

If you forget to take Orasept

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects that may occur during the period of use are listed below according to the following frequencies:

Rare (may affect up to 1 in 1 000 patients):

- hypersensitivity reactions: Hypersensitivity to lidocaine may manifest itself as accumulation of fluid in the skin and/or mucous membranes accompanied by itching, itchy skin rash, difficulty breathing, low blood pressure with syncope.

Unknown (cannot be determined from available data):

- swelling of the throat

- nausea
- a burning or itching sensation in the mouth or throat
- swelling of the mouth
- taste disorders
- increased concentration of methaemoglobin in blood
- skin rash

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Orasept

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Orasept contains

- The active substances are amylmetacresol, 2,4-dichlorobenzyl alcohol and lidocaine hydrochloride. Each lozenge contains 0.6 mg of amylmetacresol, 1.2 mg of 2,4-dichlorobenzyl alcohol and 2.0 mg of lidocaine hydrochloride.
- The other ingredients are 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 benzenecetic acid).

What Orasept looks like and contents of the pack

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

PVC-PVDC/Aluminium blisters.

Pack sizes: 16, 20, 24, 30 and 36 lozenges.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:

Dr. Max Pharma s.r.o.

Na Florenci 2116/15

Nové Město

110 00 Praag 1

Tsjechië

Fabrikant:

Lozy's Pharmaceuticals S.L.
Zona Campus Empresarial Lekaroz 1
31795 Lekaroz
Navarra
Spanje

In het register ingeschreven onder RVG 133500

This medicine is authorised in the Member States of the European Economic Area under the following names:

Czech Republic	Orasept Plus
Italy	Orasept
Nederland	Orasept 0,6 mg/1,2 mg/2 mg zuigtabletten
Poland	Septofar Plus
Romania	Septofar Plus 0,6 mg/1,2 mg/2 mg pastile
Slovak Republic	Orasept Plus

Deze bijsluiter is voor het laatst goedgekeurd in februari 2026.