

Package leaflet: Information for the user

<Product Name> mint lozenges

<Product Name> orange lozenges

<Product Name> honey & lemon lozenges

Lidocaine Hydrochloride/ Amylmetacresol/ 2, 4-Dichlorobenzyl Alcohol

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, pharmacist or nurse have 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, pharmacist or nurse. 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 <Product name> is and what it is used for
2. What you need to know before you take <Product name>
3. How to take <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

1. What <Product name> is and what it is used for

<Product name> contains amylmetacresol and 2, 4 dichlorobenzyl alcohol – both antiseptics, and lidocaine hydrochloride – a local anaesthetic for the throat.

Indicated for the local relief of symptoms of 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 <Product name>

Do not take <Product name>:

- if you are allergic to lidocaine hydrochloride or other amide-type local anaesthetic drugs, amylmetacresol, 2, 4 dichlorobenzyl alcohol or any of the other ingredients of this medicine (listed in section 6).
- Children under 12 years old should not take this medicine.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking <Product name>.

You should inform your doctor if:

- You suffer from asthma.
- Your symptoms do not improve after two days or if you have a fever, headaches, nausea, vomiting or skin rash.

This product may be harmful for the teeth.

- The anesthetics 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 and drinking hot foods.

- 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 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.
- This medicine should not be used in the area of mouth and throat if greater acute wounds exist.

<Product name> contains 1.016 g of glucose per lozenge, which should be considered when treating patients with glucose-galactose malabsorption and patients with diabetes mellitus.

<Product name> contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

<Product name> contains 1.495 g of sucrose per lozenge, which should be considered when treating patients with glucose-galactose malabsorption and patients with diabetes mellitus.

<Product name> contains terpenes found in levomenthol. Excessive doses of terpenes have been associated with neurological complications such as convulsions in children.

Sunset Yellow and Cochineal red Colourant may cause allergic reactions.

Children and adolescents

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

Other medicines and <Product name>

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, as it may be necessary to adjust their doses:

- Beta blockers (used to treat heart failure or arterial disease) or medicines containing cimetidine (used to treat stomach ulcers).
- Other local anaesthetics (amides).
- Medicines used to treat heart disorders, such as mexiletine or procainamide.
- Medicines such as fluvoxamine (used to treat depression).
- Antibiotics, such as erythromycin or itraconazole.

Although no interactions should occur, do not take other mouth or throat antiseptics while using <Product name>.

<Product name> with food, drink and alcohol

Do not take this medicine before meals or before drinking.

Pregnancy and breast-feeding

Pregnancy:

The use of this medicine is not advised during pregnancy.

Breast-feeding:

The use of this medicine is not advised during period of lactation.

Driving and using machines

Observe your response to this medicine. Taken at the recommended dose, this medicine should not affect your reactions or cause drowsiness. However, if you observe either of these effects, avoid driving or operating heavy machinery.

3. How to take <Product name>

Follow the instructions contained in this leaflet. Always take this medicine exactly 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: dissolve one lozenge slowly in the mouth every 2 to 3 hours, up to a maximum of 8 lozenges over 24 hours (maximum of 4 lozenges for children). Do not dissolve in the sac of the cheek.

Use in children and adolescents

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

If you take more <Product name> than you should

Events that may occur in the event of misuse or overdose: excessive anesthesia of the upper digestive and respiratory tract, insomnia, restlessness, excitement, respiratory depression. Shortness of breath, headache, fatigue, exercise intolerance, dizziness and loss of consciousness may also occur due to a disorder called Methemoglobinemia. Seek medical help immediately, or call the Toxicology Information Service specifying the medicine and the amount taken.

It is not recommended to use this medicine over more than 5 days, as it may alter the natural microbial balance of the throat.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. During the period of use, the following adverse reactions have been reported for the combination of active substances in this medicinal product:

You should stop taking <Product name> and see your doctor immediately if you experience symptoms of angioedema, such as

- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulties to breath

Immune system disorders

Rare (may affect up to 1 in 1,000 people): hypersensitivity reactions (burning, itching), angioedema, stinging of the throat and unpleasant taste.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

<The national reporting system per country will be addressed at national phase>

5. How to store <Product name>

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 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 <Product name> contains

The active substances are:

Lidocaine hydrochloride	2.00 mg
Amylmetacresol	0.60 mg
2,4-dichlorobenzyl alcohol	1.20 mg

The other ingredients are:

Mint lozenges

Mint oil, partly dementholised,
Star anise oil,
Levomenthol,
Indigo carmine (E-132),
Quinoline yellow (E-104),
Sodium saccharin (E-954),
Tartaric acid (E-334),
Sucrose,
Liquid glucose.

Orange lozenges

Levomenthol,
Sodium saccharin (E-954),
Sucrose,
Liquid glucose,
Sunset yellow (E-110),
Cochineal red (E-124),
Citric acid monohydrate (E-330),
Orange flavour.

Honey & lemon lozenges

Mint oil, partly dementholised,

Quinoline yellow (E-104),
Sodium saccharin (E-954),
Tartaric acid (E-334),
Sucrose,
Liquid glucose,
Sunset yellow (E-110),
Lemon essence,
Honey flavour.

What <Product name> looks like and contents of the pack

<Product Name> mint lozenges are green, biconvex, cylindrical, 19 mm diameter, mint-flavoured lozenges.

<Product Name> orange lozenges are orange, biconvex, cylindrical, 19 mm diameter, orange-flavoured lozenges.

<Product Name> honey & lemon lozenges are yellow, biconvex, cylindrical, 19 mm diameter, honey and lemon-flavoured lozenges.

PVC-PVDC/Aluminium blisters.

24 lozenges.

Marketing authorisation holder and Manufacturer

<[To be completed nationally]>

This medicinal product is authorised in the Member States of the EEA under the following names:

<[To be completed nationally]>

This leaflet was last revised in {MM/YYYY}

<[To be completed nationally]>