

Package leaflet: Information for the user

Chloralieve™

Honey & Lemon Flavour

2mg / 0.6mg / 1.2mg lozenges

Lidocaine Hydrochloride / Amylmetacresol / 2,4-Dichlorobenzyl Alcohol

Chloralieve™

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

1. What Chloralieve™ is and what it is used for

Chloralieve Honey & Lemon Flavour lozenges (referred to as Chloralieve in this leaflet) contains amylmetacresol and 2,4-dichlorobenzyl alcohol – both antiseptics, and lidocaine hydrochloride – a local anaesthetic for the throat. Chloralieve is indicated for the local relief of symptoms of sore throat in adults and children 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 Chloralieve™.

Do not take Chloralieve:

- 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 Chloralieve. 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 anesthetic 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.

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

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

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

Sunset Yellow Colourant may cause allergic reactions.

Children and adolescents

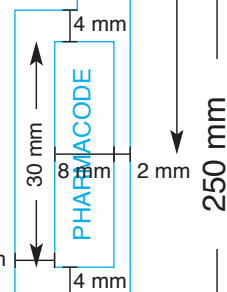
This medicine is not to be used in children under 12 years of age.

Other medicines and Chloralieve

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 Chloralieve.



125 mm

250 mm

XXXXXX

Chloralieve with food, drink and alcohol

Do not take this medicine before meals or before drinking.

Pregnancy and breast-feedingPregnancy:

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 Chloralieve™

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 children 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 Chloralieve 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 Chloralieve and see your doctor immediately if you experience symptoms of angioedema, such as

- swollen face, tongue or pharynx
- difficulty swallowing
- hives and difficulty breathing

Immune system disorders

Rare (may affect up to 1 in 1,000 people):

hypersensitivity reactions (burning, itching), stinging of

the throat and unpleasant taste.

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 the national reporting system: Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Chloralieve™

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 Chloralieve contains**

The active substances are:

Lidocaine hydrochloride	2 mg
Amylmetacresol	0.6 mg
2,4-dichlorobenzyl alcohol	1.2 mg

The other ingredients are:

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 Chloralieve looks like and contents of the pack

Chloralieve Honey & Lemon Flavour lozenges are yellow, biconvex, cylindrical, 19 mm diameter, honey & lemon flavoured lozenges.

PVC-PVDC/Aluminium blisters. 12 or 24 lozenges.

Marketing authorisation holder and Manufacturer

Marketing Authorisation Holder:

Prestige Brands (UK) Ltd., 5-7 London Road, St. Albans, AL1 1LA, UK.

Manufacturer:

Lozy's Pharmaceuticals S.L., 31795 Lekaroz (Navarra), Spain or
MAE Holding B.V, 5211 TW's-Hertogenbosch, The Netherlands or
Kymos Pharma Services, S.L., Cerdanyola del Vallès 08290, (Barcelona), Spain or
Terapia SA, Str. Fabricii nr. 124, Cluj-Napoca, Romania.

This leaflet was last revised in October 2020

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PL18259/0012

CDALHLV14201020