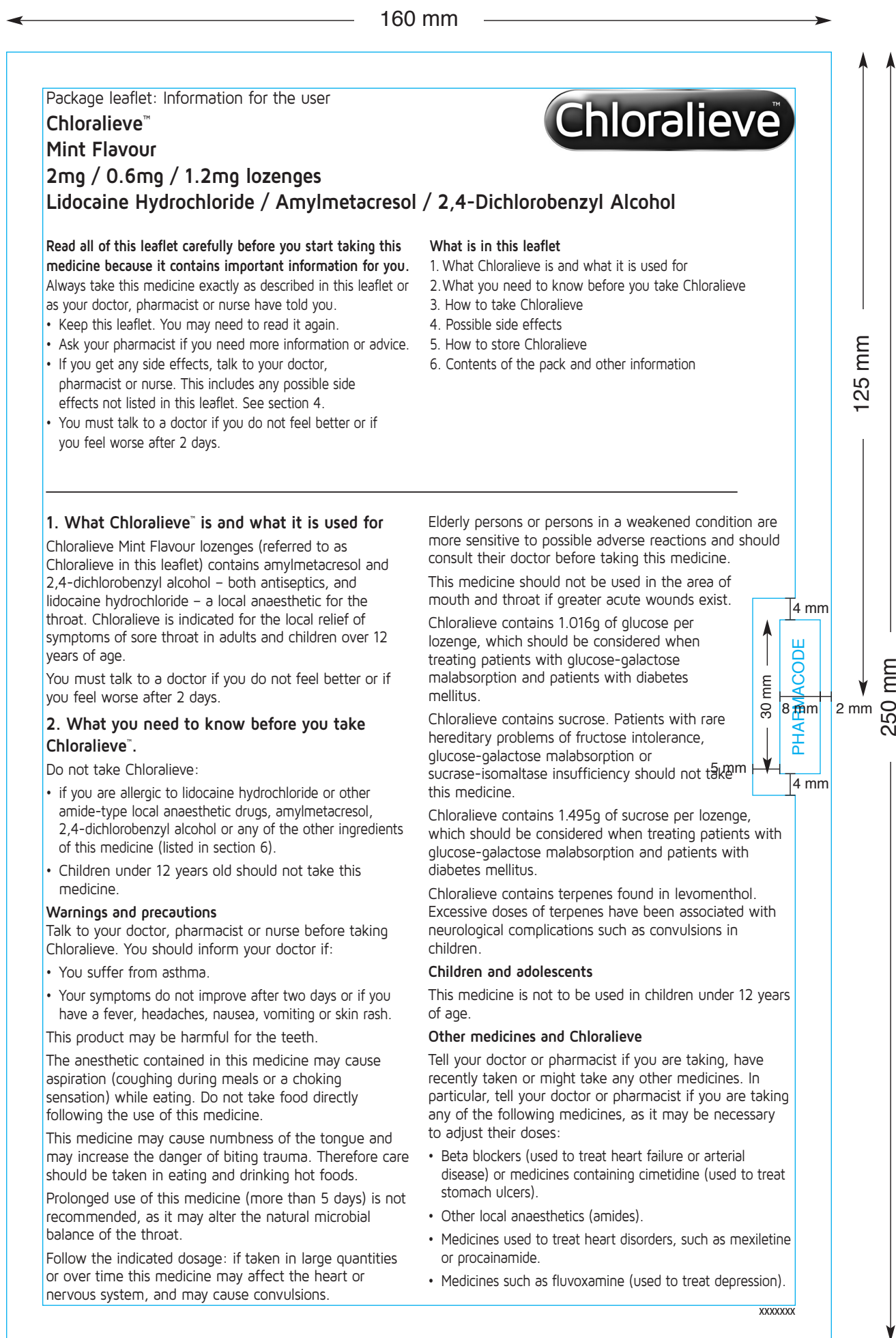


Anverso:



Reverso:

160 mm

- Antibiotics, such as erythromycin or itraconazole.

Although no interactions should occur, do not take other mouth or throat antiseptics while using Chloralieve.

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

What Chloralieve looks like and contents of the pack

Chloralieve Mint Flavour lozenges are green, biconvex, cylindrical, 19 mm diameter, mint 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, Abcoude, 1391 AB, The Netherlands or
Kymos Pharma Services, S.L., Cerdanyola del Vallès 08290, (Barcelona), Spain.

This leaflet was last revised in February 2019

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PL18259/0010

CDALMV12060219

250 mm

Artwork reference guide

file name	CDALM PIL V12 06.02.19 draft		
product	Chloralieve Mint flavour lozenges		
item	Leaflet	colours	Black only
status	Draft		
version	V12		
date	06.02.19	dimensions	160x250mm