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Package leaflet: Information for the user

Chloralieve™
Blackcurrant 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 Blackcurrant 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 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 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.
- If you have a history of allergy to local anaesthetics such as lidocaine, bupivacaine, and ropivacaine.
- If you have a history of or are suspected to have a blood condition called methaemoglobinaemia.

Warnings and precautions
 Talk to your doctor, pharmacist or nurse before taking Chloralieve. You should inform your doctor if:

- You suffer from asthma or narrowing of the airways (bronchospasm).
- 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 (see section "If you take more Chloralieve than you should").

• 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.

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 (drugs for certain bacterial infections), such as erythromycin or antimycotics (medicines against certain fungal infections), such as 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, breast-feeding and fertility
 The use of this medicine is not advised during pregnancy and lactation. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
 Observe your response to this medicine. Taken at the

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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.

Chloralieve contains glucose, sucrose, cochineal red and black PN.
Chloralieve contains sucrose and glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Chloralieve contains 1.016 g of glucose per lozenge. This should be taken into account in patients with diabetes mellitus.
Chloralieve contains 1.495 g of sucrose per lozenge. This should be taken into account in patients with diabetes mellitus.
Cochineal red Colourant and black PN colourant may cause allergic reactions.

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 lowest efficient dose should be used over the shortest duration to achieve a resolution of symptoms. 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. Not recommended for children under 12 years. No adjustment of dosage is necessary in elderly patients.

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. Other serious side effects of lidocaine overdose include: low blood pressure, low heart rate or heart stopping, breathing stopping and starting or stopping completely, seizures, coma, cardiac arrest and death. Seek medical help immediately, or call the Toxicology Information Service specifying the medicine and the amount taken.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Treatment:
Treatment should be symptomatic and supportive; medical supervision is advisable.
Methemoglobinemia (presence of methemoglobin in the blood) may be treated by immediate intravenous injection of methylene blue (1-4 mg/kg).

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

- Hypersensitivity: Hypersensitivity to lidocaine may manifest itself as accumulation of fluid in the skin and/or mucous membranes accompanied by itching, itchy skin rash, bronchospasms, hypotension with syncope.
- swelling of the mouth and throat
- abdominal pain, nausea, oral discomfort, burning sensation of tingling in the mouth of the throat, disruption of the taste.
- skin rash

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 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 | 2.00 mg |
| Amylmetacresol | 0.60 mg |
| 2,4-dichlorobenzyl alcohol | 1.20 mg |

The other ingredients are:
Levomenthol, Sodium saccharin (E-954), Sucrose, Liquid glucose, Black PN (E-151), Cochineal red (E-124), Citric acid monohydrate (E-330), Blackcurrant flavour

What Chloralieve looks like and contents of the pack
Chloralieve Blackcurrant Flavour lozenges are purple biconvex, cylindrical, 19 mm diameter, blackcurrant flavoured lozenges.
PVC-PVDC/Aluminium blisters. 12 or 24 lozenges.

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.

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