SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chloralieve Mint Flavour 2mg / 0.6mg / 1.2mg lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:	
Lidocaine Hydrochloride	2.00 mg
Amylmetacresol	0.60 mg
2, 4-Dichlorobenzyl Alcohol	1.20 mg
Excipients with known effect:	
Sucrose	1,495.85 mg
Liquid glucose	1,016.82 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenge

Chloralieve Mint Flavour lozenges are green, biconvex, cylindrical, 19 mm diameter, mint-flavoured lozenges.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Relief of symptoms of sore throat in adults and adolescents over 12 years of age.

4.2 Posology and method of administration

Posology

Adults and children over 12 years of age:

1 lozenge every 2-3 hours, and when necessary, up to a maximum of 8 lozenges in a 24-hour period (maximum of 4 lozenges for children).

Paediatric population:

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

Method of administration

For oromucosal use.

Slowly dissolve the lozenge in the mouth, do not dissolve in the sac of the cheek.

Do not take this medicine before meals or drinking.

The prolonged use of this medicine for more than 5 days is not recommended (see section 4.4).

Elderly: Adjustment of the dose is not required.

Patients with impaired renal and/or liver function: There are no data available for use of Chloralieve Mint Flavour lozenges in patients with hepatic or renal impairment.

4.3 Contraindications

- Do not use Chloralieve Mint Flavour Lozenges in children under 12 years of age due to the risk of rapid absorption of the anaesthetic and the risk of reflex laryngospasm.
- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1
- A history of allergy to local anaesthetics of the amide type.
- In patients who have a history of or are suspected to have methaemoglobinaemia.

4.4 Special warnings and precautions for use

If symptoms do not improve or become worse after 2 days, contact a doctor or pharmacist.

Follow the indicated dosage: when taken in large amounts or repeatedly, this medicine may impact the nervous system as it passes through the bloodstream, possibly causing convulsions or affecting the heart.

The prolonged use of this medicine for more than 5 days is not recommended, as it may alter the natural microbial balance of the throat.

If symptoms persist for longer than 2 days, get worsen or if other symptoms appear, such as high fever, headache, nausea or vomiting, and skin rash, the clinical condition should be evaluated for bacterial infections (angina, tonsillitis).

It should be administered with caution in acutely ill or frail elderly patients, as they are more sensitive to adverse reactions to this medicinal product.

In susceptible patients, due to the local anaesthetic effect, the risk of choking may increase, or the sensitivity of the mouth or throat may temporarily be modified.

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

The anaesthesia of the throat caused by this medicinal product may lead to pulmonary aspiration (coughing while eating, giving the impression that the person is choking). It is therefore imperative not to take this medicine before meals or drinking.

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

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

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

Chloralieve Mint Flavour lozenges contains terpenes found in levomenthol. Excessive doses of terpenes have been associated with neurological complications such as convulsions in children.

Chloralieve Mint Flavour lozenges 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. The patient should be aware that the production of topical anesthesia may impair swallowing and thus enhance the danger of aspiration. For this reason, food should not be ingested directly following use of local anesthetic preparations in the mouth or throat area.

4.5 Interaction with other medicinal products and other forms of interaction

While a number of interactions are theoretically possible with lidocaine, these drug interactions are unlikely to be clinically relevant to the safety of the patient as the product is administered topically:

The toxicity of orally administered lidocaine may be increased with concomitant administration of the following substances:

-Erythromycin

-Itraconazole

-Cimetidine

-Fluvoxamine

-Beta-blockers

-Other antiarrhythmics (e.g. mexiletine)

- Beta-adrenergic blocking agents reduce the hepatic blood flow and therefore the speed at which lidocaine is metabolised, resulting in a greater risk of toxicity.

- Cimetidine can inhibit the hepatic metabolism of lidocaine, resulting in a greater risk of toxicity.

- It can cause cross-sensitivity to other local anesthetics of the amide type (see section 4.3).

- Class III antiarrhythmics, such as mexiletine and procainamide, due to potential pharmacokinetic or pharmacodynamic interactions.

- The isoenzymes CYP1A2 and CYP3A4 of the cytochrome P450 are involved in the formation of MEGX, the pharmacologically active metabolite of lidocaine, and therefore other medications such as fluvoxamine, erythromycin and itraconazole may increase the plasma concentrations of lidocaine.

- The simultaneous or successive use of other antiseptics is not advised, due to possible interference (antagonism, deactivation).

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of Chloralieve Mint Flavour lozenges in pregnancy has not been established.

A large amount of data on the local use of lidocaine during pregnancy indicates no increased risk of congenital malformations or foetal/neonatal toxicity of lidocaine. Lidocaine passes the placenta; however, there is very little absorption as a result of the low dose. Animal studies do not indicate reproductive toxicity (see section 5.3).

There are no data on the use of amylmetacresol and 2,4-Dichlorobenzyl Alcohol as pharmacologically active substances during pregnancy. In the absence of documented experience, the use of Chloralieve Mint Flavour lozenges is not recommended during pregnancy.

Breast-feeding

The safety of Chloralieve Mint Flavour lozenges during the period of lactation has not been established. Lidocaine is excreted in small amounts in breast milk. Because of the low dose, no effect of lidocaine on the infant is anticipated. There are no data on the excretion of amylmetacresol and 2,4-Dichlorobenzyl Alcohol in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Chloralieve Mint Flavour lozenges therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility

There are no data on the effect of use of lidocaine, amylmetacresol and 2,4-Dichlorobenzyl Alcohol on male and female fertility.

4.7 Effects on ability to drive and use machines

This medicinal product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

During the period of use, the following adverse reactions have been reported for the combination of active substances in this medicinal product:

During treatment of chronic conditions and with long-term use additional side effects may occur.

The adverse reactions associated with the combination of active substances in this medicinal product are described below by system organ class and ranked according to frequency: very common (≥ 1/10), common (≥ 1/100, < 1/10), uncommon (≥ 1/1,000, < 1/100), rare (≥1/10,000, < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data)

System Organ Class	Frequency	Adverse events

Immune system disorders	Rare	Hypersensitivity reactions[1] (burning, itching), angioedema, urticaria, bronchospasm, hypotension, stinging of the throat and unpleasant taste
Respiratory, thoracic and mediastinal disorders	Not known	Pharyngeal edema
Gastrointestinal disorders	Not known	Nausea, oral discomfort, swelling of the mouth, dysgeusia.
Skin and subcutaneous tissue disorders	Not known	Rash

Description of Selected Adverse Reactions

[1] Hypersensitivity reactions to lidocaine may present in the form of angioedema, urticaria, bronchospasms and hypotension with syncope.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

Given the low level of the active ingredients, overdose is unlikely.

In case of abnormal use (much higher dosage, lesions of the mucous membranes), overdose may occur. This is manifested initially by excessive anaesthesia of the upper respiratory and digestive tract. Systemic reactions due to the absorption of lidocaine can occur. The most serious effects of lidocaine include intoxication in the central nervous system (insomnia, restlessness, excitement and respiratory depression) and the cardiovascular system; also methaemoglobinaemia may occur.

Treatment

In the event of an overdose, induction of vomiting, and / or gastric lavage (within one hour) in case of a potentially serious intoxication, may be considered. Additional measures are only used on supportive and symptomatic basis.

Methaemoglobinaemia can be treated by immediate intravenous injection of methylene blue (1-4 mg/kg).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Throat Preparations, Antiseptics, various.

ATC code: R02AA20.

The combination of active ingredients in Chloralieve Mint Flavour lozenges provides local antiseptic, bactericidal, fungicidal and analgesic properties.

This medicinal product contains:

- 2, 4-Dichlorobenzyl alcohol and amylmetacresol, have antiseptic actives against the pathogenic bacterial flora of the oral cavity. Both substances belong to the chemical group of alcohols and phenols respectivelyproperties.
- Lidocaine is a local anesthetic of the amide type, provides rapid, intense and prolonged pain relief.

5.2 Pharmacokinetic properties

Lidocaine has a half-life of 1 to 2 hours (around 100 minutes), which is dependent on the dose. The half-life of the metabolite glycinexylidide (GX) is longer, and therefore accumulation may occur, especially in case the excretion is renal.

There are no relevant data on the pharmacokinetics of either 2,4-dichlorobenzyl alcohol or amylmetacresol with the exception of a bioavailability study reported in the summary of product characteristics of Benagol (Benagol, 2008) which determines the rapid release of both antiseptics in the saliva, reaching maximum levels in 3-4 minutes after sucking the lozenge.

The amount of 2,4-alcohol dichlorobenzyl and amylmetacresol found in the saliva after 120 minutes is approximately 50% of the amount administered.

In patients with myocardial infarction (with or without heart failure), the half-life of lidocaine and monoethylglycinexylidide (MEGX) is extended; the half-life of (GX) may also be lengthened in patients with heart failure secondary to myocardial infarction. A longer half-life has also been reported for lidocaine in patients with congestive heart failure or liver disease and may last longer following continuous IV infusion lasting more than 24 hours. The elimination of MEGX may also be decreased in patients with congestive heart failure.

Lidocaine is readily absorbed through the mucous membranes. The plasma elimination half-life is approximately 2 hours. Once absorbed, it undergoes significant first-pass metabolism in the liver, and is rapidly de-ethylated to the active metabolite monoethylglycinexylidide, which is then hydrolysed to various metabolites, including glycinexylidide. Less than 10% is excreted unchanged by the kidneys. The metabolites are also excreted in the urine.

5.3 Preclinical safety data

Non-clinical data on 2,4-dichlorobenzyl alcohol and amylmetacresol revealed no special hazard for humans. These data come from conventional studies of single and repeated dose toxicity, genotoxicity and toxicity to reproduction. Studies on safety pharmacology and carcinogenicity have not been performed.

Genotoxicity studies with lidocaine were negative. The carcinogenicity of lidocaine has not been studied. The lidocaine metabolite 2,6-xylidine has genotoxic potential in vitro. In a carcinogenicity study of rats exposed to 2,6-xylidine in utero, postnatally and throughout their lifetime, tumours in the nasal cavity, subcutaneous tumours and liver tumours were observed. The clinical relevance of tumour findings in relation to short-term/intermittent use of lidocaine is unknown.

In animal studies on reproduction toxicity, there was no evidence of teratogenic effects or evidence of adverse events in the physical development of the offspring following prenatal treatment with lidocaine. However, foetal exposure to high doses of lidocaine affected uterine blood flow and caused foetal convulsions.

Otherwise, non-clinical data on lidocaine do not add any relevant information to the existing clinical experience.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

27 months.

6.4 Special precautions for storage

Do not store above 30ºC.

6.5 Nature and contents of container

PVC-PVDC/Aluminium blisters

24 lozenges

6.6 Special precautions for disposal

Any unused medicinal product and all material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Prestige Brands (UK) Ltd

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St. Albans

AL1 1LA,

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL18259/0010

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