

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vocasept sugar free lemon flavour 0.6mg / 1.2mg lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:

Amylmetacresol	0.60 mg
2, 4-Dichlorobenzyl Alcohol	1.20 mg

Excipients with known effect:

Maltitol: 473.34 mg /lozenge

Isomalt: 1893.36 mg / lozenge

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenges.

Vocasept sugar free lemon flavour is white to pale yellow colored, lemon-flavoured lozenges.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of mouth and throat infections

4.2 Posology and method of administration

Posology

Use the lowest dose for the shortest duration necessary to relieve symptoms.

Adults: 1 lozenge every 2 or 3 hours, as needed, up to a maximum of 12 lozenges in 24 hours.

Paediatric population

Children over 6 years: as above for adults.

Vocasept sugar free lemon flavour should not be used in children under 6 years of age. (See Section 4.4)

Elderly: Adjustment of the dose is not required.

The prolonged use of this medicine for more 3 days is not recommended.

Method of administration

For oromucosal use

Allow the lozenge to dissolve slowly in the mouth. Do not swallow, chew or bite. Lozenges should not be used just before or during meals.

4.3 Contraindications

Hypersensitivity to the active substances or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

The use of Vocasept sugar free lemon flavour is not recommended for children under 6 years of age.

If symptoms persist, have not improved, or have worsened after 3 days, consult a doctor or health care professional.

Excipients with known effect:

Vocasept sugar free lemon flavour may have a mild laxative effect. Calorific value 2.3 kcal/g maltitol and isomalt. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

This medicinal product contains less than 1 mmol sodium (23 mg) per lozenge, that is to say essentially "Sodium-free".

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions are known

4.6 Fertility, pregnancy and lactation

Pregnancy:

There are no or limited amount of data from the use of amylmetacresol and 2,4-dichlorobenzyl alcohol.

As with all medicines care should be taken when using this product in pregnancy and medical advice sought if necessary.

Breastfeeding:

It is unknown whether 2,4-dichlorobenzyl alcohol, amylmetacresol or metabolites are excreted in human milk. A risk to the newborns / infants cannot be excluded.

Fertility

There are no data on the effect of use of amylmetacresol and dichlorobenzyl alcohol on fertility.

4.7 Effects on ability to drive and use machines

Vocasept sugar free lemon flavour has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

The list of the following adverse effects relates to those experienced with 2,4-dichlorobenzyl alcohol and amylmetacresol at OTC doses, in short term use.

Adverse events which have been associated with 2,4 dichlorobenzyl alcohol and amylmetacresol are given below, tabulated by system organ class and frequency. Frequencies are defined as:

Very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$) or not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

Immune system Disorders	<u>Not known</u> Hypersensitivity ^{ab1}
Gastrointestinal Disorders	<u>Not known</u> Glossodynia ^{ab} , oral discomfort ^{ab}

^a2,4-dichlorobenzyl alcohol ^bamylmetacresol

¹ Hypersensitivity reactions may include rash, urticaria and angioedema, which may include swelling of the face, neck, throat or tongue that could affect breathing.

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 at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

In view of the nature and presentation of Vocasept sugar free lemon flavour, accidental or deliberate overdosage is highly unlikely.

Overdosage should not present a problem other than gastrointestinal discomfort.

Treatment

Overdose treatment should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Throat preparations - Antiseptics

ATC Code: R02AA03 Dichlorobenzyl alcohol.

2,4-dichlorobenzyl alcohol and amylmetacresol are antiseptics and possess antibacterial (bactericidal and bacteriostatic), antifungal and antiviral

properties as demonstrated in vitro. When the two active agents are combined, a synergistic antibacterial action is observed leading to a reduced combined dose.

In-vitro studies demonstrated killing effects against some sore throat causing organisms such as Streptococcus pyogenes, Staphylococcus aureus, Haemophilus influenza and Moraxella catarrhalis, at 1 minute contact time. An overall reduction in the oral bacterial load was also seen in one in-vivo study.

In-vitro antiviral action against enveloped viruses including influenza A virus, para-influenza virus, respiratory syncytial virus, cytomegalovirus and coronavirus has also been observed for both AMC and DCBA as well as the combination of the two after 1-2 minutes contact.

In clinical studies, there was evidence that AMC and DCBA lozenges led to reduction of throat soreness, and provided relief from pain and difficulty in swallowing, with onset of activity in 5 minutes and lasting for up to 2 hours. Significantly more relief than non-medicated lozenge was also demonstrated for up to 3 days treatment. In one study, AMC and DCBA lozenges have also been shown to significantly decrease post-operative throat soreness and hoarseness 20 minutes and 24 hours after intubation. A study in children (6-16 years) with acute and recurring chronic sore throat demonstrated a reduction in subjective and objective signs of sore throat over 3 days of treatment with AMC and DCBA lozenges.

Vocasept sugar free lemon flavour Lozenges have a soothing and calming effect on the mucous membrane of the throat.

5.2 Pharmacokinetic properties

Not available

5.3 Preclinical safety data

No carcinogenic, mutagenic or teratogenic effects have been described in preclinical studies.

In rats, the LD50 for dichlorobenzyl alcohol was determined to be 3 g per kg body weight.

On the basis of these data, a single daily dose of 100 mg/kg bw for dichlorobenzyl alcohol in humans was derived according to the NOAEL (the highest dose at which adverse effects have not yet been observed).

Animal studies indicate no adverse effects on the course of pregnancy or on fetal development

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium (E954)
Isomalt (E953)
Maltitol, liquid (E965)
Lemon flavour
Tartaric acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years

6.4 Special precautions for storage

No special storage conditions are required.

6.5 Nature and contents of container

PVC-PVDC/Aluminium blister. Each pack contains 8, 16 and 24 lozenges.
Not all package sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should be disposed of in

accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Mapaex Consumer Healthcare (Ireland) Private Limited
IDA Business Park, Green Road, Newbridge
KILDARE
W12 X902
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 57980/0006

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

28/01/2026

10 DATE OF REVISION OF THE TEXT

28/01/2026