Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan 0.6 mg/1.2 mg mint lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 0.6 mg amylmetacresol and 1.2 mg 2,4-dichlorobenzyl alcohol.

Excipients with known effect
Each lozenge contains 1.83 g of isomalt (E953) and 0.46 g of maltitol liquid (E965).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenge

A green, round, mint flavoured lozenge with a diameter of 19 mm ± 1 mm.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of mouth and throat infections.

4.2 Posology and method of administration

Posology

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. It is recommended that the product should be used for a maximum of 3 days.

Adults
One lozenge every 2 or 3 hours, as needed, up to a maximum of 8 lozenges in 24 hours.

Paediatric population

Children over 6 years of age
One lozenge every 2 or 3 hours, as needed up to a maximum of 4 lozenges in 24 hours, with a minimum of 2 hours between the lozenges.

Children under 6 years of age
Amylmetacresol/2, 4-Dichlorobenzyl alcohol Mylan should not be used in children under 6 years (see section 4.4.)

Elderly
There is no need for dosage reduction in the elderly.

Method of administration

For oromucosal administration. To be dissolved slowly in the mouth. Do not swallow, chew or bite.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

This product is not recommended for young children due to a risk of choking (see section 4.2).
Patients should be advised to consult the doctor if symptoms persist or if anything unusual happens.

Excipients
This medicinal product contains isomalt (E953), maltitol liquid (E965) and sodium.
Patients with rare hereditary problems of fructose intolerance should not take this medicine. Isomalt (E953) and maltitol liquid (E965) have a calorific value 2.3 kcal/g and may have a mild laxative effect.
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 (less than 300 pregnancy outcomes) from the use of amylmetacresol and 2,4-dichlorobenzyl alcohol in pregnant women. As a precautionary measure, it is preferable to avoid the use of Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan during pregnancy.

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
No data are available regarding the effects on fertility.
However, animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

4.7 Effects on ability to drive and use machines

No adverse effects are known.

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. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

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 (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity
Gastrointestinal Disorders	Not known	Abdominal pain, nausea, oral discomfort
Skin and Subcutaneous Tissue Disorders	Not known	Rash

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 HPRA Pharmacovigilance. Website: www.hpra.ie.

4.9 Overdose

Overdosage should not present a problem other than gastrointestinal discomfort.
Treatment should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Throat preparations; Antiseptics, ATC code: R02AA03 Dichlorobenzyl alcohol.

Mechanism of action
2,4-Dichlorobenzyl alcohol and amylmetacresol are antiseptics and possess antibacterial, antifungal and antiviral properties. Both AMC and DCBA also reversibly block depolarisation-induced ion channels in a similar way to local anaesthetics. When the two active agents are combined, a synergistic antibacterial action is observed leading to the reduced combined dose used in this type of products.

Clinical efficacy and safety
Evidence of an analgesic effect for the combination of 2,4-dichlorobenzyl alcohol and amylmetacresol in reducing throat soreness, providing pain relief and relief from difficulty in swallowing has been demonstrated to clinical studies with an onset in 5 minutes which lasts for up to 2 hours. Significantly more relief than nonmedical lozenge was also demonstrated for up to 3 days treatment.

The combination of 2,4-dichlorobenzyl alcohol and amylmetacresol have also been shown to significantly decrease postoperative 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 demonstrates a reduction in subjective and objective signs of sore throat over 3 days.

The combination of 2,4-dichlorobenzyl alcohol and amylmetacresol has a demulcent action providing throat soothing.

5.2 Pharmacokinetic properties

None available.

5.3 Preclinical safety data

None available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Peppermint oil
Star anise oil
Levomenthol
Indigo carmine 190 (E132)
Quinoline yellow (E104)
Sodium saccharin (E954)
Tartaric acid (E334)
Isomalt (E953)
Maltitol liquid (E965)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

The lozenges are packaged in PVC-PVDC/Aluminium blisters.

Each pack contains 16 or 24 lozenges.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McDermott Laboratories Ltd., T/A Gerard Laboratories
35/36 Baldoyle Industrial Estate
Grange Road
Dublin 13
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0577/192/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th February 2021
Date of Last renewal: 18th December 2025

10 DATE OF REVISION OF THE TEXT

May 2025