

## Package leaflet: Information for the patient

### Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan 0.6 mg/1.2 mg honey & lemon lozenges

amylmetacresol  
2,4-dichlorobenzyl alcohol

#### **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 or pharmacist 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 or pharmacist. 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 3 days.

#### **What is in this leaflet**

1. What Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan is and what it is used for
2. What you need to know before you take Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan
3. How to take Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan
4. Possible side effects
5. How to store Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan
6. Contents of the pack and other information

#### **1. What Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan is and what it is used for**

Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan contains amylmetacresol and 2,4-dichlorobenzyl alcohol. These ingredients are both mild antiseptics and are used for the symptomatic relief of mouth and throat infections.

The action of sucking the lozenge allows the active ingredients to work in the area of the discomfort and also helps lubricate and soothe the painful area. This helps relieve the soreness and discomfort of mouth and throat.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

#### **2. What you need to know before you take Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan**

This medicine is recommended for adults, children (over 6 years old) and the elderly. Children under 6 years old should not use this product.

#### **Do not take Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan:**

- if you are allergic to amylmetacresol, 2,4-dichlorobenzyl alcohol, sunset yellow (E110) or any of the other ingredients of this medicine (listed in section 6).

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan if you suffer or are suffering from any other throat problems.

You should not use this product for a long period of time.

Generally, sore throat is a mild disease that lasts no longer than a week. Contact your doctor if the symptoms persist for longer than 3 days, get worsen or if other symptoms appear as they may need to be treated in a different way.

### **Children and adolescents**

Due to the size of the lozenges young children can choke on Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan.

Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan must not be given to children under 6 years.

### **Other medicines and Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

There are no known significant interactions.

### **Pregnancy, breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicinal product may not be suitable for you.

### **Driving and using machines**

There are no known side effects of this medicine that may influence your ability to drive or use machines.

### **Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan contains isomalt (E953), maltitol liquid (E965), sunset yellow (E110) and sodium**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Isomalt (E953) and maltitol (E965) have a calorific value 2.3 kcal/g and may have a mild laxative effect.

Sunset yellow (E110) may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per lozenge, that is to say essentially 'sodium-free'.

## **3. How to take Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

#### *Adults*

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

#### *Elderly*

There is no need for reducing the dose in the elderly.

### **Use in children**

#### *Children over 6 years old*

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 old*

This medicine is not suitable for children under 6 years old.

Dissolve the lozenges slowly in the mouth. Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan should not be swallowed, chewed or bitten.

**If you take more Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan than you should**

If you exceed the recommended dosage, you may experience gastrointestinal discomfort. Do not take any more of this product and consult your doctor or pharmacist.

**If you forget to take Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan**

Continue to use this product normally.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any hypersensitivity to this product, stop taking this product and consult your doctor or pharmacist. If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**Not known** (frequency cannot be estimated from the available data)

- Hypersensitivity reactions (symptoms may include rash, burning, itching, swelling of the mouth or throat).
- Pain in the tummy (abdominal pain).
- Nausea.
- Oral discomfort.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance.

Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan**

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.

This medicine does not require any special storage conditions.

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 Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan contains**

- The active substances are amylmetacresol and 2,4-dichlorobenzyl alcohol.  
Each lozenge contains 0.6 mg amylmetacresol and 1.2 mg 2,4-dichlorobenzyl alcohol.

- The other ingredients are peppermint oil, quinoline yellow (E104), sodium saccharin (E954), tartaric acid (E334), isomalt (E953), maltitol liquid(E965), sunset yellow (E110), lemon essence (lemon essence contains contains lemon oil, terpene and citral) and honey flavour (honey flavour contains propylene glycol).

**What Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan looks like and contents of the pack**

Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan 0.6 mg/1.2 mg honey & lemon lozenges are orange-yellow, round and honey-lemon flavoured.

Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan is packed in blisters with 16 or 24 lozenges.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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

**Manufacturer**

LOZY'S PHARMACEUTICALS, S.L, Campus Empresarial 31795 Lekaroz (Navarra), Spain

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Ireland	Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan 0.60 mg/1.2 mg honey & lemon lozenges
Italy	FROBEN ANTISETTICO GOLLA
Slovakia	Oroakut

**This leaflet was last revised in 12/2020.**