

Package leaflet: Information for the patient

Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan 0.6 mg/1.2 mg mint 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
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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 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 worse 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) 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 liquid (E965) have a calorific value 2.3 kcal/g and may have a mild laxative effect.

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 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 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. 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), star anise oil, levomenthol and indigo carmine 190 (E132).

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 mint lozenges are green, round and mint 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 mint lozenges
Italy	FROBEN ANTISETTICO GOLA
Slovakia	Oroakut

This leaflet was last revised in 12/2020.