

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

Medijel oromucosal gel  
Lidocaine hydrochloride 0.66% w/w  
Aminoacridine hydrochloride 0.05% w/w

### **Read all of this leaflet carefully before you start using Medijel because it contains important information for you.**

Always use this medicine as described in this leaflet or as your doctor, pharmacist, nurse or dentist has 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, pharmacist, nurse or dentist. 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 7 days.

### **WHAT IS IN THIS LEAFLET**

1. What Medijel is and what it is used for
2. What you need to know before you use Medijel
3. How to use Medijel
4. Possible side effects
5. How to store Medijel
6. Contents of the pack and other information

### **1. WHAT IS MEDIJEL AND WHAT IS IT USED FOR**

Medijel contains two active substances, Lidocaine Hydrochloride and Aminoacridine Hydrochloride. Lidocaine Hydrochloride is one of the most widely used local anaesthetics. Aminoacridine Hydrochloride is a disinfectant and is used to treat local infections of the mouth.

Medijel is used to provide quick effective relief from pain of common mouth ulcers, soreness of gums and denture rubbing. Medijel is used in adults and children from 6 years.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE MEDIJEL**

**Do not take Medijel if** you are allergic to Lidocaine or any of the excipients in this medicine (listed in section 6).

#### **Warnings and precautions**

If symptoms persist for more than 7 days, consult your doctor or dentist.

#### **Children and adolescents**

Do not give this medicine to children under 6 years of age.

#### **Pregnancy and lactation**

The safety of Medijel during pregnancy and lactation has not been established, but is considered not to constitute a hazard.

#### **Driving and using machines**

Medijel has no influence on the ability to drive and use machines.

**Medijel contains sucrose and alcohol**

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

Contains small amounts of ethanol (alcohol) less than 100mg per dose.

**3. HOW TO USE MEDIJEL**

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

Medijel should be applied directly to the affected area(s) with a clean finger or small pad of cotton wool.

**Adults and adolescents over 12 years of age**

Massage a pea-sized amount of gel onto the affected area. If necessary application may be repeated after 20 minutes and then at three hourly intervals up to a maximum of eight times daily.

**Children (from 6 years)**

Massage a pea-sized amount of gel onto the affected area, no more frequently than every three hours and up to a maximum of 6 times daily.

**Not suitable for children under 6 years.**

If symptoms persist for more than 7 days consult your doctor or pharmacist.

**If you take more Medijel than you should**

If you have taken more Medijel than you should, or if for example a child has taken the medicine by accident, contact your doctor immediately.

The experience of overdose with Medijel is limited but reported symptoms include dizziness, a drop in blood pressure, muscular tremors, convulsions, coma, irregular and weak breathing, cardiac standstill and bronchospasm. 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. Allergic reactions have been rarely reported with preparations containing Lidocaine. Seek medical attention immediately if you have any of these signs of an allergic reaction: hives, difficulty breathing, swelling of your face, lips, tongue or throat.

Should irritation develop, discontinue use.

**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, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971 Fax: +353 1 6762517 Website: [www.hpra.ie](http://www.hpra.ie) e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

**5. HOW TO STORE MEDIJEL**

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 and tube. The expiry date refers to the last day of the month.

Do not store above 25°C.

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 Medijel contains**

- The active substances are Lidocaine Hydrochloride 0.66% and Aminoacridine Hydrochloride 0.05%. Each dose is approximately 300mg, i.e. 2mg of Lidocaine Hydrochloride and 0.15mg of Aminoacridine Hydrochloride.
- The other ingredients are:
  - Sucrose, Ethanol (96%), Carbomer, Diisopropanolamine 90% Aqueous, Hydroxypolyethoxydodecane, Peppermint Oil, Ethyl Vanillin, Saccharin Sodium, Glycerol, Purified Water.

### **What Medijel looks like and the contents of the pack**

Medijel is presented as a soft green, slightly opalescent, oromucosal gel. Medijel is packaged in aluminium tubes with a membrane seal and spiked polyethylene cap. Available in pack sizes of 12.5g and 15g. Not all pack sizes may be marketed.

### **Marketing authorisation holder**

Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland.

### **Manufacturer**

Dendron Brands Limited, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK.

This leaflet was last revised in March 2021.