

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

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

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine hydrochloride 0.66 % w/w.

Aminoacridine hydrochloride 0.05 % w/w.

Excipients: also contains 32 % w/w sucrose and 9.0 % w/w ethanol.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oromucosal gel

Soft green, slightly opalescent gel.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the quick and effective relief from the pain of common mouth ulcers, soreness of gums and denture rubbing.

### 4.2 Posology and method of administration

The gel 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 small (up to 1 cm diameter) pea-sized amount of gel (approximately 300 mg) onto the affected area. (300 mg of gel contains 2 mg lidocaine hydrochloride and 0.15 mg aminoacridine hydrochloride).

If necessary application may be repeated after 20 minutes and then at three hourly intervals up to a maximum of eight times daily (The total amount of lidocaine is 16mg following 8 applications).

Children (from 6 years): Massage a small (up to 1 cm diameter) pea-sized amount of gel onto the affected area, no more frequently than every three hours and up to a maximum of six applications daily (The total amount of lidocaine is 12mg following 6 applications).

Not suitable for children under 6 years.

### 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

### 4.4 Special warnings and precautions for use

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

Contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

#### **4.5 Interaction with other medicinal products and other forms of interactions**

None stated.

#### **4.6 Fertility, pregnancy and lactation**

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

#### **4.7 Effects on ability to drive and use machines**

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

#### **4.8 Undesirable effects**

Hypersensitivity reactions to Lignocaine have been reported on rare occasions.

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, 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).

#### **4.9 Overdose**

The toxic effects of Lidocaine are directly related to blood concentrations. Symptoms are dizziness, fall of blood pressure, muscular tremors, convulsions, coma, irregular and weak breathing, cardiac standstill and bronchospasm. Induced emesis followed by activated charcoal is only useful if the patient is seen within 30 minutes of ingestion. The primary resuscitation aim is airway maintenance. Artificial respiration with oxygen should be given until convulsions or respiratory depression are controlled and blood pressure and pulse return to normal.

Convulsions can be controlled with i.v. diazepam or i.v. succinylcholine chloride. Perform artificial respiration with oxygen until convulsions are controlled and continue giving oxygen until blood pressure and pulse return to normal. Adequate arterial oxygen saturation must be maintained. If convulsions are not continuous the administration of oxygen may be sufficient to maintain the patient until the blood level of lidocaine falls. Do not give stimulants. Methaemoglobinaemia can be treated by i.v. methylene blue. Treat fall in blood pressure by postural means (head down, feet raised, supine position) or with i.v. saline or blood transfusion if shock threatens.

Suppression of pharyngeal sensation with concomitant effects on swallowing may theoretically result from excessive topical oral use of Medijel Gel. Such an effect has been reported in an adult who gargled and swallowed 5 ml of a 2% Lidocaine hydrochloride solution (equivalent to 100 mg of Lidocaine). However, assuming proportionality of body surface area and pharyngeal surface area, this dose would be equivalent to a single dose of 33.75 g of Medijel Gel for a 75 kg adult.

The Lidocaine hydrochloride content of a 12.5 g tube and a 15 g tube of Medijel Gel are 82.5 mg and 99 mg respectively. It is most unlikely, even with misuse or excessive application of Medijel Gel that the large amounts of Lidocaine hydrochloride required to produce clinically-relevant toxic effects would be reached. In the event of overdose, use should be discontinued and a doctor consulted.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Lignocaine Hydrochloride is well documented in Martindale 28<sup>th</sup> Edition Page 900-904 and Goodman & Gillman, Chapter 15 and pages 767-770.

Lignocaine Hydrochloride was first introduced in 1948 and is one of the most widely used local anaesthetics, however it produces more prompt, more intense, longer lasting and more extensive anaesthesia than does an equal concentration of procaine (Peak anaesthesia within 2-5 minutes). Local anaesthetics are drugs that block nerve conduction when applied locally to nerve tissue in appropriate concentrations. They have good powers of penetration and their action is reversible. Their use is followed by complete recovery in nerve function with no evidence of structural damage to nerve fibres or cells.

Aminacrine Hydrochloride is a slow acting disinfectant. It exerts germicidal action against bacteria and fungi. It is used as a surgical and endodontic irrigant and to treat local infections of the ear, mouth and throat. Its exact mode of action is not known but it involves disruption of certain metabolic pathways.

### 5.2 Pharmacokinetic properties

Lignocaine is readily absorbed through mucous membranes. They exert their effects in the form of the non-ionised base. Lignocaine undergoes first-pass metabolism in the liver and bioavailability is low after administration by mouth. It is rapidly de-ethylated to the active metabolite monoethylglycinexylidide and then hydrolysed by amidases to various compounds, including glycineexylidide which has reduced activity but a longer elimination half life. Less than 10% of a dose is excreted unchanged via the kidneys. The metabolic products are excreted in the urine.

Aminacrine Hydrochloride if administered systemically is rapidly eliminated through the kidney (0.2 grams being eliminated from the blood in 30 minutes). Medijel Gel dose 0.15mg aminacrine Hydrochloride).

### 5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Glycerol  
Hydroxy polyethoxydodecane  
Ethanol (96%)  
Carbomer  
Sucrose  
Saccharin Sodium  
Peppermint Oil  
Di-isopropanolamine 90% aqueous  
Ethyl Vanillin  
Purified Water

### 6.2 Incompatibilities

Not applicable.

### **6.3 Shelf life**

4 years.

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

Aluminium tube with membrane seal and spiked polyethylene cap.  
Pack size: 12.5 g and 15 g.

Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

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

## **8 MARKETING AUTHORISATION NUMBER**

PA1113/022/001

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

Date of first authorisation: 30 April 1984

Date of last renewal: 30 April 2009

## **10 DATE OF REVISION OF THE TEXT**

February 2021