

# ZIAGEL - GINGIVAL GEL

## QUANTATIVE AND QUALITATIVE COMPOSITION

Per 100 g of gel

Lignocaine .....	5.00 g
Cetrimide .....	0.15 g

Saccharin, Cochineal red, artificial cherry flavour, mint flavour, Polyethylene glycol 4000, Polyethylene glycol 300

## DOSAGE FORM

Gingival gel

## PHARMACO-THERAPEUTIC CLASS

**DENTAL PRODUCT FOR PROFESSIONAL USE** : Topical anaesthetic agent

## WHERE SHOULD THIS MEDICINE BE USED

Topical anaesthesia of the oral mucosa

Available in mint & cherry flavours - cherry is particularly attractive to children

## CAUTION !

### CONTRA-INDICATIONS

- Patients allergic to Lignocaine anaesthetic
- Children under 4 years of age

### SPECIAL WARNINGS

After applying the anaesthetic agent on the mucosa, it is important to expel the surplus product so not to swallow it.

### PREGNANCY-LACTATION

Risk-benefit should be carefully considered before administering to pregnant or breast-feeding women – adequate and well-controlled studies in humans have not been done and it is not known whether the active ingredients are excreted in breast milk.

### SPORTS PEOPLE

Sports people should be warned that this drug contains an active ingredient likely to induce a positive reaction to tests undertaken during anti-doping controls.

## **HOW TO USE THIS MEDICINAL PRODUCT**

### **INSTRUCTIONS**

ZIAGEL gingival gel should be applied on the mucosa previously dried. The gel is applied according to the designed instructions using a cotton pellet at the rate of 0.10 to 0.20 g of finished product per application viz 5 to 10 mg of Lignocaine per application.

The daily applicable maximum dose should not exceed 4 g of gel at 5% or 200mg of lignocaine base corresponding to a length of about 18 cm. In persons weighing 70 kg the maximum dose represents 2.9 mg of lignocaine base per kilo.

The maximal dose should be recalculated from this base in some particular cases such as adults in bad health.

### **METHOD & WAY OF ADMINISTRATION**

To be applied topically on to a mucosa previously dried.

### **UNDESIRABLE & DISCOMFORTING EFFECTS (SIDE/ADVERSE EFFECTS)**

The toxic reactions (non documented in this pharmaceutical form used topically) may occur under two conditions : either immediately by relative overdosage owing to an inadvertent intravascular passing, or later by actual overdosage owing to a too large quantity of anaesthetic agent administered.

This could result in

*As regards the Central Nervous System* : nervousness, restlessness, yawning, trembling, apprehension, nystagmus, logorrhoea, headache, nausea, tinnitus. Careful attention is necessary when these symptoms appear in order to prevent possible worsening such as convulsions then depression of the CNS.

*As regards the respiratory system* : tachypnea, then dyspnea.

*As regards the cardiovascular system* : tachycardia, hypertension likely to be followed by signs of depression, hypotension, bradycardia leading up to cardiac arrest.

### **SHELF LIFE**

**DO NOT USE AFTER THE EXPIRY DATE MENTIONED ON THE EXTERNAL PART OF THE PACKAGE**

### **SPECIAL PRECAUTIONS FOR STORAGE**

The storage temperature of the product should not exceed 25°C

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

May 26, 2009