

## Physician's Prescribing Information

### **ALVOGYL** **Paste for Dental Use**

The format of this leaflet was decided by the Israeli Ministry of Health and its contents was checked and approved

#### **IDENTIFICATION OF THE MEDICINAL PRODUCT**

**Qualitative and Quantitative Composition:** Lidocaine 5.0 % ; Eugenol 15.0 %

Excipients: Sodium Lauryl Sulphate, Calcium Carbonate, Penghawar Djambi, Olive Oil, Purified Water, Natural Mint Flavour.  
Q.s. ad 100 g of paste for dental use.

**DOSAGE FORM:** Paste for dental use. Jar of 12 g.

#### **CLINICAL PARTICULARS**

**Therapeutic Indications:** Additional treatment of alveolitis after verification and cleaning of the socket.

**Posology and Method of Administration:** Local use only. A small pellet of ALVOGYL should be applied aseptically to cover the bottom of the socket after verification and cleaning the socket.

Do not treat more than 5 teeth in one session.

**Contraindications:** Allergy to one of the ingredients of the formula in particular to lidocaine or to local anaesthetics.

Allergy to Eugenol. Not to be used on deciduous teeth (children under 12 years of age).

**Special Warnings and Special Precautions for Use:** ALVOGYL is not resorbable, therefore never stitch up after setting the product into place. Patients should be told not to wash their mouth vigorously within the 24 hours following the avulsion. Do not ingest.

Sports people should be warned that this product contains an active ingredient likely to induce a positive reaction to tests undertaken in antidoping controls.

**Interactions with Other Medicaments and Other Forms of Interactions:** Lidocaine should be used with caution in patients receiving anti-arrhythmic drugs, such as tocainide, since the toxic effects are additive.

**Pregnancy and Lactation:** The safe use of lidocaine and Eugenol has not been established with respect to possible adverse effects upon foetal development. The use of ALVOGYL in pregnant and nursing mothers should be outweighed against the risk-benefit possibilities.

Lidocaine is excreted in breast milk and so should be used with caution in nursing women.

**Effect on Ability to Drive and Use Machines:** Depending on the dose, lidocaine and local anaesthetics may have a very mild effect on mental function and may temporarily impair locomotion and co-ordination.

**Undesirable Effects:** Risk of allergy.

Adverse experiences following the administration of Lidocaine are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage or rapid absorption, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature.

**Overdose:** In normal conditions of use in dental practice, no overdose effect has ever been reported.

#### **PHARMACOLOGICAL PROPERTIES**

**Pharmacodynamic Properties:** FOR PROFESSIONAL USE ONLY IN DENTAL PRACTICE

(A : digestive tract and metabolism)

Lidocaine : local anaesthetic.

Eugenol : antiseptic and analgesic.

The anaesthetic action lasts a few hours, then the product gradually self eliminates.

**Pharmacokinetic Properties:** Lidocaine is rapidly distributed to all body tissues. About 65% is plasma bound. Lidocaine crosses the placenta and the blood brain barrier. The plasma half life is 1.6 hours. About 80% of the dose is metabolised in the liver; less than 10% is found unchanged in the urine.

**Preclinical Safety Data:** Not applicable since lidocaine and eugenol have been used in clinical practice for many years and their effects in man are well known.

#### **PHARMACEUTICAL DATA**

**Incompatibilities:** None stated.

**Storage instructions:** Do not store above 25°C.

**Nature and contents of container:** 17.7-ml opal glass jar (Type III) filled to 15 ml and plugged with a low density polyethylene obturator. Each glass jar contains 12 g of paste.

**Israeli Drug Registration Number:** 130.65.30919.00

**Manufacturer:** Laboratoires SEPTODONT, France

**Agent & Importer:** A. Levy Dental Co. Ltd., 27 Kalisher street, Tel Aviv 65165

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