

Physicians Prescribing Information

CRESOPHENE, Solution for dental use

The format and contents of this leaflet were determined, checked and approved by the Israeli Ministry of Health

Trade Name of the Medicinal Product: CRESOPHENE

Qualitative and Quantitative Composition: Active ingredients: Dexamethasone Acetate 0.111 % and Thymol 5.00 % in a solution for dental use. Excipients: Parachlorophenol, Camphor.

Pharmaceutical form: Solution for dental use.

Therapeutic Indications: Root canal antiseptics before filling.

Posology and Method of Administration: For local dental use only. After avulsion of the gangrened pulp and thorough reaming, insert a solution – impregnated cotton plug into the canal. Prior to insertion wring out the plug to eliminate excess solution.

Temporarily seal the canal with non-compressive impervious cement. Leave in place for 3 to 5 days.

If necessary, repeat the procedure after debriding and reaming the root canal using the usual methods.

Contraindications: Children under 30 months of age ; Allergy to any constituent, particularly corticosteroids and phenols.

Special Warnings and Special Precautions for Use:

Warnings: In the event of contact with the mucosa, rinse thoroughly with water.

Special precautions for use: Do not swallow ; Do not impregnate the cotton plug to excess ; Do not apply to exposed pulp.

Interactions with Other Medicinal Products and Other Forms of Interaction: None known.

Pregnancy and Lactation: Safe use of CRESOPHENE during pregnancy and lactation has not been established with respect to adverse effects on foetal development. Careful consideration should be given to this fact before administering this drug in pregnant and lactating women. It is not known whether CRESOPHENE is excreted in breast milk.

Effects on Ability to Drive and Use Machines: None known.

Undesirable Effects: Risk of allergy

Overdose: In the event of overdose or misuse in dentistry, phenols may cause excessive periapical inflammation and periodontitis

Pharmacological Properties:

Pharmacodynamic Properties: For Professional Use Only in Dentistry.

Group A: Gastrointestinal tract and metabolism

Dexamethasone: anti-inflammatory, corticosteroid. Thymol: antiseptic

Incompatibilities: None Known.

Shelf-life: Do Not use after the expiry date mentioned on the outer package.

Special Precautions for Storage: Do not store above 25°C.

Nature and Contents of Container: 15-ml amber glass vial (type III) closed with an aluminium tear-off cap fitted with a polyethylene gasket (type Triseal ®)

Pack-Size: 13-ml (amber glass) bottle + dispensing stopper (aminoplastic + low-density polyethylene)

Instructions for Use / Handling: After first use, replace the aluminum cap by the dispensing stopper supplied in the box.

Israeli Drug Registration Number: 135.58.31115.00

Manufacturer: Septodont, France.

Israeli Marketing Authorization Holder & Importer: A. Levy Dental Co. Ltd., VAT # 510917768, 27

Kalisher street, Tel-Aviv 65165

Last revised: 21.11.2006