

## SUMMARY OF PRODUCT CHARACTERISTICS

### PRODUCT SUMMARY

#### 1. NAME OF THE MEDICINAL PRODUCT

CAUSTINERF FORTE  
DEVITASOL FORTE

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Paraformaldehyde	46.00 %
Lidocaine Base	37.00 %
Phenol	6.00 %

#### 3. PHARMACEUTICAL FORM

Paste

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Devitalisation of dental pulp.

##### 4.2 Posology and Method of Administration

Route of Administration  
Local

##### Recommended Dose

Apply aseptically a pellet (about 10 mg of paste) to the pulp, after having removed the carious dentine and exposed the pulp.  
Seal with a cement and open again after 7 to 10 days.  
Then, if necessary, repeat the treatment.  
After extirpation of the pulp and treatment of the canals, the tooth can be filled permanently.

The product is to be used only twice at the most, at the above mentioned dose, in the treatment of any one tooth.

##### 4.3 Contra-Indications

CAUSTINERF FORTE should not be used in patients with a history of allergic reaction to amide type anaesthetics.

##### 4.4 Special Warnings and Precautions for Use

##### Warnings

Following the application of CAUSTINERF FORTE, the cavity must be carefully sealed with a cement to prevent any leaching of the product.  
Leaching can cause local destruction of the periodontium and necrosis of bone.  
It may also cause transitory but painful mucosal ulcers.

##### Precautions for Use

Contents should be used within one year of opening. The cap should always be replaced immediately after use and the jar kept in a cool dry place.

##### 4.5 Interactions with Other Medicaments and Other Forms of Interaction

None stated.

##### 4.6 Pregnancy and Lactation

Not stated.

#### **4.7 Effects on Ability to Drive and Use Machines**

None stated.

#### **4.8 Undesirable Effects**

None stated.

#### **4.9 Overdose**

None reported.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic Properties**

CAUSTINERF FORTE is a paste intended for the devitalisation of dental pulp. It contains an antiseptic, paraformaldehyde, which effectively coagulates albumins, and lignocaine, which reduces pain.

Phenol, also present in the formula, intensifies the hardening effect of paraformaldehyde and, furthermore, it increases the antiseptic effect of the preparation.

The application of CAUSTINERF FORTE without arsenic induces a fibrous change in the pulp which facilitates its extirpation after a few days, (7 to 10 days on average), the pulp having taken a paper-like consistency.

#### **5.2 Pharmacokinetic Properties**

Not applicable.

#### **5.3 Preclinical Safety Data**

Not applicable.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of Excipients**

Polyethylene fibers, vinyl chloride acetate copolymer, titanium dioxide.

#### **6.2 Incompatibilities**

None stated.

#### **6.3 Shelf-life**

18 months.

The product should be used within 12 months of first opening.

#### **6.4 Special Precautions for Storage**

Store below 25°C.

#### **6.5 Nature and Contents of Container**

Direct container:

Opal white opaque glass jar, with a thread at the top. Capacity : 7 ml.

Closures:

A screw cap in hard white plastics (urea formaldehyde) is fitted onto the jar. A transparent sealing liner is attached to the interior of the cap. This liner is made of expanded polyethylene, enclosed between two films of massive polyethylene. A plastic insert is in contact with the paste.

Contents:

4.5 g

#### **6.6 Instructions for Use/Handling**

See 4.2. "Posology and Method of Administration"

## **ADMINISTRATIVE DATA**

### **7. MARKETING AUTHORISATION HOLDER**

SEPTODONT UK Ltd.  
Units R & S  
Orchard Business Centre,  
St Barnabas Close,  
Allington, Maidstone  
Kent ME16 0JZ  
ENGLAND

### **8. MARKETING AUTHORISATION NUMBER**

PL 08313/0025

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

20/01/1988 – 16/04/1998

### **10. DATE OF (PARTIAL) REVISION OF THE TEXT**

May 2001.