

**FREJESIC CREAM**  
**MENTHOL, EUCALYPTUS OIL, METHYL SALICYLATE AND TURPENTINE OIL**  
**CREAM** **INDIA**

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**1.3.1 Summary of Product Characteristics (SmPC)**

**1. Name of Medicinal Product**

**FREJESIC CREAM**

**MENTHOL, EUCALYPTUS OIL, METHYL SALICYLATE AND TURPENTINE OIL**  
**CREAM**

**2. Qualitative and Quantitative Composition**

**2.1. Qualitative declaration:**

Menthol BP

Eucalyptus oil BP

Methyl salicylate BP

Turpentine oil BP

**2.2. Quantitative declaration:**

**Composition of the Drug product:**

Menthol BP .....5.19 % w/w

Eucalyptus oil BP..... 1.97% w/w

Methyl salicylate BP .....12.80% w/w

Turpentine oil BP.....1.47% w/w

Cream Base .....Q.S.

**Qualitative & Quantitative Composition Formula:**

**Batch Size: 300 KG**

CLAROID PHARMACEUTICALS PVT. LTD.  
Survey No.217/P Opp.Gurukul English medium School Kamod,  
Satpanth Mandir Pirana Road, TA,  
Ahmedabad-382425, Gujarat India.

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Sr. No	Name of Ingredients	Spec.	% content % w/w	Std. Qty per batch (in kg)
<b>Aqueous Phase</b>				
01	Sodium Metabisulfite	BP	0.10	0.300
02	Carbomer-940	USP/NF	1.00	3.000
03	Triethanolamine	USP/NF	1.50	4.500
<b>Oil Phase</b>				
04	Methyl Salicylate	BP	12.80	41.472** (38.400 + 8%)
05	Menthol	BP	5.19	15.881* (15.570 + 2%)
06	Eucalyptus oil	BP	1.97	6.501*** (5.910 + 10%)
07	Iso Propyl Myristate	BP	1.00	3.000
08	Turpentine oil	BP	1.47	4.41
<b>Manufacturing Vessel</b>				
09	Disodium Edetate	BP	1.16	3.550 (3.480 + 2%)
10	Benzyl Alcohol	BP	1.00	3.240** (3.000 + 8%)
11	Butylated Hydroxy Toluene	BP	0.20	0.600
12	Propylene Glycol	BP	4.00	12.000
13	Iso Propyl Alcohol	BP	3.00	9.000
14	Polysorbate 80	BP	1.50	4.500
15	Purified Water	IHS	64.11	196.18# (192.33 + 2%)
Section: Ointment		Total Batch Quantity: 300.000 kg		
Note: 2% Extra Purified Water added to compensate loss during manufacturing.				

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### **3. Pharmaceutical form**

A White to off white gelatinous homogenous mass.

### **4. Clinical particulars**

#### **4.1 Therapeutic indications**

In the local management of the symptoms of fibrositis, muscle strains and arthroses.

#### **4.2 Posology and method of administration**

For adults and children over 5 years.

Directions for use: Apply a thin layer to the affected part with gentle massage 2 to 3 times daily.

#### **4.3 Contraindications**

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1

Hypersensitivity to aspirin or other non-steroidal anti-inflammatory drugs (including when taken by mouth) especially where associated with a history of asthma.

#### **4.4 Special warnings and precautions for use**

Do not use if you are allergic to any of the ingredients or medicines like aspirin. Consult your doctor before use if you are pregnant, breast-feeding, asthmatic or on any prescribed medicines. For external use and only on unbroken skin. Avoid contact with the eyes and sensitive areas of skin. Always try on a small area first. Some people may experience discomfort particularly those with sensitive skin or if used in hot weather or after a bath. Wash hands immediately after use.

This medicine contains propylene glycol. Propylene glycol may cause skin irritation.

Discontinue use if excessive irritation or other unwanted effects occur. If symptoms persist consult your doctor. Not to be used on children under 5 years of age. Keep all medicines out of the sight and reach of children

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

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Although no adequately controlled interaction studies have been undertaken, it is possible that excessive use of topical salicylates may increase the effect of coumarin anticoagulants and antiplatelet medications. It is therefore advisable that caution be exercised with patients who are on coumarin anticoagulants or antiplatelet medications, including aspirin.

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

There are no adequate data for the use of this product during pregnancy or breast-feeding upon which to base specific advice. Safety has not been established during pregnancy and lactation. Patients should seek advice from their doctor before using the product. Salicylates are aspirin-like substances; therefore similar cautions as appropriate for aspirin are advised. As with all medicinal products, use during pregnancy or breast-feeding should be avoided unless considered necessary.

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

None known

#### **4.8 Undesirable effects**

Irritation of the skin (redness, burning, swelling, blistering) may occur. Burns at application site: not known (frequency cannot be estimated from the available data). There may also be more severe allergy reported (urticaria etc).

#### **4.9 Overdose**

Not applicable.

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group:

Menthol- topical analgesic.

Eucalyptus oil - anti-inflammatory, analgesic, and antipyretic agent

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(ATC code: R05CA13)

Methyl salicylate - non-steroidal anti-inflammatory medication (NSAID).

Turpentine oil- essential oil

Methyl salicylate is absorbed through the skin and is used for the relief of pain in rheumatic condition.

Turpentine oil when applied topically acts as a rubefacient.

Eucalyptus oil when applied topically acts as a rubefacient and may also be used by inhalation in combination with menthol to relieve nasal congestion

### **5.2 Pharmacokinetic properties**

The product is for topical administration. No absorption studies have been carried out with this product. Like other salicylates, methyl salicylate may be absorbed through intact skin.

### **5.3 Preclinical safety data**

The ingredients are subject to monographs in the British and European Pharmacopoeias and are documented in Martindale, The Extra Pharmacopoeia. Therefore no pre-clinical data are included with this application.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium Metabisulfite	BP
Carbomer-940	USP/NF
Triethanolamine	USP/NF
Iso Propyl Myristate	BP
Disodium Edetate	BP
Benzyl Alcohol	BP
Butylated Hydroxy Toluene	BP
Propylene Glycol	BP
Iso Propyl Alcohol	BP
Polysorbate 80	BP

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Purified Water
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IHS
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**6.2 Incompatibilities:**

Not applicable.

**6.3 Shelf-life:** 36 months

**6.4 Special precautions for storage:**

Store at a temperature not exceeding 30 °C, Protect from heat and direct sunlight.

Keep out of reach of children.

**6.5 Nature and contents of container:**

**FREJESIC CREAM:** 30 GM Tube packed in a carton with insert.

**6.6 Special precautions for disposal and other handling**

No special instructions for disposal.

Do not swallow.

Avoid contact with eyes.

**7. Marketing Authorization Holder:**

**VENCHURA PHARMACEUTICALS LIMITED.,**

**5, Mercy Eneli Street, Surulere,**

**Lagos, Nigeria.**

**8. Marketing Authorization Number (s):**

**Product license / registration Number (s)**

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**9. Manufacturer Name:**

**Claroid Pharmaceuticals Pvt. Ltd.**

**Survey no. 217/p, opp. Gurukul English medium school,**

**Kamod pirana road,tal.daskroi,**

**Dist.- ahmedabad – 382425,**

**Gujarat, India.**

**10. Date of first authorization/renewal of the authorization:**

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**11. Date of revision of the text:**

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