

## 1. Name of the Medicinal Product

(a) **Product Name** : FEXOTEM CREAM

(b) **Pharmaceutical Dosage Form** : Cream

## 2. Quality and Quantitative Composition

(a) **Qualitative Declaration**, the active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant.

### Each gram contains:

Methyl Salicylate	BP	30% w/w
Camphor	USP	4% w/w
Menthol	USP	10% w/w
Eucalyptus Oil	USP	5% w/w
Cream base		q.s.

(b) **Quantitative Declaration**, the quantity of the active substance must be expressed per dosage unit

Sr. No.	Name of the Materials	Spec	Label Claim	Overages (%)	Quantity (mg)	Batch Qty. Kg
1	Methyl Salicylate	BP	30%w/w	---	300	90.000
2	Menthol	USP	4%w/w	---	40	12.000
3	Camphor	USP	10%w/w	---	100	30.000
4	Eucalyptus Oil	USP	5%w/w	---	50	15.000
5	Methyl Paraben Plain	BP	---	---	---	0.150
6	Propyl Paraben Plain	BP	---	---	---	0.009
7	Cetostearyl Alcohol	BP	---	---	---	24.000
8	Cetomacragol-1000	BP	---	---	---	9.000
9	Liquid Paraffin Heavy	BP	---	---	---	30.000
10	Petroleum Jelly	BP	---	---	---	30.000
11	Emulsifying Wax	BP	---	---	---	24.000
12	Purified Water	BP	---	---	---	q.s.

## 3. Pharmaceutical Form Visual description of the appearance of the product (colour, markings, etc.) e.g.:

A off white colour cream having characteristic odour, filled in 30 gm printed lami tube properly sealed and labeled.

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

#### **4.4 Special warning 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. 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 interactions:**

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 anti-platelet 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 machine:**

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:**

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

**Camphor** stimulates nerve endings that reduce symptoms like pain and itching when topically applied to the skin.

**Menthol** provides a cooling sensation when applied to the skin, which helps relieve pain.

**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:**

Not Applicable.

**6.0 Pharmaceutical Particulars**

**6.1 List of excipients:**

S.No.	Product Name	Reference
1	Methyl Paraben Plain	BP
2	Propyl Paraben Plain	BP
3	Cetostearyl Alcohol	BP
4	Cetomacragol – 1000	BP
5	Liquid Paraffin Heavy	BP
6	Petroleum Jelly	BP
7	Emulsifying Wax	BP
8	Purified Water	BP

**6.2 Incompatibilities:**

None.

**6.3 Shelf life:** 36 Months

**6.4 Special precautions for storage:**

Store protected from light and moisture, below 30°C. Do not freeze.

**6.5 Nature and contents of container:**

White colour smooth gel filled in 30 gm laminated tube. Such 1 tube is packed in a printed carton along with the insert.

**6.6 Instructions for use and handling**

No special requirements.

## **7.0 Marketing Authorization Holder**

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