1. NAME OF THE MEDICINAL PRODUCT

DEEPFIT CREAM

2. QUALITATIVE & QUANTITATIVE COMPOSITION

Qualitative

Declaration Label

Claim:

Diclofenac Diethylamine BP

Eq. to Diclofenac sodium….1.16 % w/w

Linseed oil BP...…….…….3.0% w/w

Menthol BP.....5.0 %w/w

Cream base……..q.s.

Excipients:

Diclofenac Diethylamine

Menthol

White petroleum Jelly

Light liquid paraffin

Cetostearyl Alcohol

Ceto Macrogol-1000

Carbopol-934

Propylene glycol

Benzyl Alcohol

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the local symptomatic relief of pain and inflammation in:

- Trauma of the tendons, ligaments, muscles and joints, eg due to sprains, strains and bruises
- localized forms of soft tissue rheumatism

It is recommended that the treatment be reviewed after 14 days in these indications. For the treatment of osteoarthritis of superficial joints such as the knee. In the treatment of osteoarthritis, therapy should be reviewed after 4 weeks.

4.2 Posology and method of administration

Adults: Deepfit Cream should be rubbed gently into the skin**.** Depending on the size of the affected site to be treated 2-4g (a circular shaped mass approximately 2.0-2.5cm in diameter) should be applied 3 - 4 times a daily**.**

After application, the hands should be washed unless they are the site being treated.

Use in the elderly: The usual adult dosage may be used.

Children and adolescents: There are insufficient data on efficacy and safety available for the children and adolescents below 14 years of age (see also contraindications section 4.3). In children aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

Deepfit Cream is suitable for the transmission of ultrasound and may be used as a couplant in combination with ultrasound therapy. If large areas of the body are covered with cream, systemic absorption will be greater and the risk of side-effects increased, especially if the therapy is used frequently.

4.3 Contraindications

Patients with or without chronic asthma in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid (aspirin) or other non- steroidal anti-inflammatory drugs (NSAIDs).

- Hypersensitivity to diclofenac or any of the excipients
- Third trimester of pregnancy.
- The use in children and adolescents aged less than 14 years is contraindicated.

4.4 Special warnings and precautions for use

Need as the incidence of untoward effects, particularly systemic side effects, may increase.

Deepfit Cream should not be co-administered with other products containing diclofenac.

Deepfit Cream should be applied only to intact, non-diseased skin and not to skin wounds or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes and should not be ingested.

Discontinue the treatment if a skin rash develops after applying the product.

Deepfit Cream can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

Some possibility of gastro-intestinal bleeding in those with a significant history of this condition has been reported in isolated cases.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

Since systemic absorption of diclofenac from a topical application is very low such interactions are very unlikely. There are no known interactions with Deepfit Cream but for a list of interactions known with oral diclofenac the data sheet for oral dosage forms should be consulted.

4.6 Fertility, pregnancy and

Lactation <u>Pregnancy</u>

The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. With reference to experience from treatment with NSAIDs with systemic uptake, the following is recommended:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac

malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-fatal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenesis period. During the first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary. If diclofenac is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

- Cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- Renal dysfunction, which may progress to renal failure with oligo-

hydroamniosis; The mother and the neonate, at the end of pregnancy, to:

- Possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- Inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, diclofenac is contraindicated during the third trimester of

pregnancy. **Lactation**

Like other NSAIDs, diclofenac passes into breast milk in small amounts. However, at therapeutic doses of Deepfit Cream no effects on the suckling child are anticipated. Because of a lack of controlled studies in lactating women, the product should only be used during lactation under advice from a healthcare professional. Under this circumstance, Deepfit Cream should not be applied on the breasts of nursing mothers, nor do elsewhere on large areas of skin or for a prolonged period.

4.7 Effects on ability to drive and use machines.

Cutaneous application of Deepfit Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent first, using the following convention: very common (> 1/10); common ≥ (1/100, <1/10); uncommon ≥(1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (<1/10,000), not known: cannot be estimated from the available data.

Table 1

Immune system disorder:	
Very rare:	Hypersensitivity (including urticaria), angioneurotic oedema.
Infections and infestations:	
Very rare:	Rash pustular.
Respiratory, thoracic and mediastinal disorders	
Very rare:	Asthma.
Skin and subcutaneous tissue disorders	
Common:	Rash, eczema, erythema, dermatitis (including dermatitis contact), pruritus
Rare:	Dermatitis bullous
Very rare:	Photosensitivity reaction

Although less likely with the topical administration, some side effects normally associated with systemically administered diclofenac may also occur.

4.9 Overdose

Signs and symptoms

The low systemic absorption of Deepfit Cream renders overdose very unlikely. However, undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if Deepfit Cream is inadvertently ingested (1 tube of 100g contains the equivalent of 1000mg of diclofenac sodium). In the event of accidental ingestion, resulting in significant systemic adverse effects, general therapeutic measures normally adopted to treat poisoning with non- steroidal anti-inflammatory medicines should be used. Gastric decontamination and the use of activated charcoal should be considered, especially within a short time of ingestion

Treatment

Management of over dosage with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from Voltarol overdosage. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro-intestinal irritation, and respiratory depression; specific therapies such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive

metabolism.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical products for joint and muscular pain, anti-inflammatory preparations, non-steroids for topical use. Deepfit Cream is a non-steroidal anti-inflammatory (NSAID) and analgesic preparation designed for external application. Due to an aqueous-alcoholic base the cream exerts a soothing and cooling effect.

Mechanism of Action of Menthol

Menthol acts as a local anesthetic on the respiratory passageways and causing cough suppression. When Menthol is rubbed on the skin, it acts as a rubefacient and causes localized vasodilatation; which gives feelings of comfort and warmth. When applied gently on the skin, it acts as an anti-pruritic agent and creates a feeling of coolness, and mild local anaesthetic effect relieves itching. It has good soothing effect and acts as a demulcent. It also acts as a carminative.

5.2 Pharmacokinetic properties

When Deepfit Cream is applied locally, the active substance is absorbed through the skin. In healthy volunteers approximately 6% of the dose applied is absorbed, as determined by urinary excretion of diclofenac and its hydroxylated metabolites. Findings in patients confirm that diclofenac penetrates inflamed areas following local application of Deepfit Cream.

After topical administration of Deepfit Cream to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid. Maximum plasma concentrations of diclofenac are about 100 times lower than after oral administration of Voltarol.

5.3 Preclinical safety data

None known.

6. Pharmaceutical particulars

6.1 List of excipients

White petroleum jelly, Light liquid paraffin,

Cetostearyl Alcohol, Cetomacrogol 1000,

Carbopol-934, Propylene glycol & Benzyl Alcohol.

6.2 Incompatibilities: Not Applicable.

6.3 Shelf life: 36 months.

6.4 Special precautions for storage

Store below 30 ^{0} C.

6.5 Nature and contents of container

30 g Lami tube filled and sealed to be packed in a primary carton along with the Pack Insert.

6.6 Special precautions for disposal and other handling

No special requirements for disposal. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 **Manufacturer:**
Name & address:
LESANTO LABORATORIES
Plot No. 9,10,11 & 20,
Survey No. 53,
Palghar (E) – 401 404,
Maharashtra, India.

8. **Marketing Authorizations Holder**:
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