

### **1.3 Product Information**

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

**1. NAME OF THE MEDICINAL PRODUCT**

INFLANIL, Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate and Menthol Gel

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Diclofenac Diethylamine BP 1.16% w/w  
Eq. to Diclofenac Sodium BP 1.00% w/w  
Linseed Oil BP 3.0% w/w/  
Methyl Salicylate BP 10% w/w  
Menthol BP 5.0% w/w  
Gel Base q.s.

For full list of excipients, see section 6.1

**3. PHARMACEUTICAL FORM**

Gel for topical administration  
A white colour smooth gel filled in laminated tube.

**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
- localised 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**

For cutaneous use only

*Adults and children 14 years and over:* INFLANIL 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) of gel should be applied 3 - 4 times a day.

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.

INFLANIL 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 gel,

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 asthma, angioedema, 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**

The possibility of experiencing systemic adverse events (those associated with the use of systemic forms of diclofenac) from application of INFLANIL cannot be excluded if the preparation is used at higher dosage/large amounts over large areas of skin and over a prolonged period (see the product information on systemic forms of diclofenac e.g. oral or injection for systemic adverse reactions).

Concomitant use of systemic NSAIDs should be cautioned since the possibility of an increase in incidence of untoward effects, particularly systemic side effects, cannot be ruled out.

INFLANIL contains propylene glycol and benzyl benzoate, which may cause mild, localised skin irritation in some people.

Like other drugs that inhibit prostaglandin synthetase activity, diclofenac and other NSAIDs can precipitate bronchospasm if administered to patients suffering from or with a previous history of, bronchial asthma.

INFLANIL 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.

Patients should be warned against excessive exposure to sunlight in order to reduce the incidence of photosensitivity.

INFLANIL 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 INFLANIL, 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**

##### **Fertility**

There are no data available on the use of topical formulations of diclofenac and its effects on fertility in humans.

##### **Pregnancy**

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-fetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic 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 fetus 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 INFLANIL 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, INFLANIL should not be applied on the breasts of nursing mothers, nor elsewhere on large areas of skin or for a prolonged period of time (see section 4.4).

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

Cutaneous application of INFLANIL 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  $\geq$  ( 1/100, <1/10);

uncommon  $\geq(1/1,000, < 1/100)$ ; rare ( $\geq 1/10,000, <1/1,000$ ); very rare ( $<1/10,000$ ), not known: cannot be estimated from the available data.

*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

Not known: Desquamation, skin discolouration

***Reporting of suspected adverse reactions***

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

#### **4.9 Overdose**

##### **Signs and symptoms**

The low systemic absorption of INFLANIL renders overdose very unlikely. However, undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if INFLANIL is inadvertently ingested (e.g. 1 tube of 100g contains the equivalent of 1000 mg of diclofenac sodium).

##### **Treatment**

Management of overdosage with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from INFLANIL 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.

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. The use of activated charcoal should be considered, especially within a short time (within one hour) of ingestion of a toxic dose.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

#### **Pharmacotherapeutic group:**

Topical products for joint and muscular pain, anti-inflammatory preparations, non-steroids for topical use (ATC code M02A A15).

Diclofenac is a potent non-steroidal anti-inflammatory drug (NSAID) with effective analgesic, anti-inflammatory and antipyretic properties. Diclofenac exerts its therapeutic effects primarily through inhibition of prostaglandin synthesis by cyclo-oxygenase 2 (COX-2).

This medicine is an anti-inflammatory and analgesic preparation designed for topical application. In inflammation and pain of traumatic or rheumatic origin, relieves pain and decreases swelling.

Due to an aqueous-alcoholic base the gel exerts a soothing and cooling effect.

### **5.2 Pharmacokinetic properties**

When INFLANIL 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 INFLANIL. From the skin and underlying tissue, diclofenac preferentially distributes and persists in deep inflamed tissues (such as the joint), rather than in the bloodstream.

After topical administration of INFLANIL 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 INFLANIL.

### **5.3 Preclinical safety data**

None known

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Propylene Glycol  
Benzyl Alcohol  
Sodium methyl paraben  
Shellpol 940  
HPMC E 15  
Purified water

### **6.2 Incompatibilities**

None.

### **6.3 Shelf life**

36 months

### **6.4 Special precautions for storage**

Store below 30C. Protect from light and moisture.

INFLANIL should be kept out of reach and sight of children.

### **6.5 Nature and contents of container**

Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate and Menthol Gel is packed in 30 gm and 50 gm laminated tube and packed. One tube is packed in carton along with package insert.

This is available in packs of 10g, 15g, 30g, 50 g and 100g. Not all pack sizes may be marketed.

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

None.

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**7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE  
ADDRESSES**

**Applicant**

SAM PHARMACEUTICAL LTD.

8/9, Oyadiran Estate, Sabo, Yaba-Lagos, Nigeria.

**Manufacturer:**

UNIZA LIFECARE PRIVATE LIMITED

SR. No. 919/7, (Old SR. No.404), Kadi-Detroj Road, Balasar,

Tal: Kadi, Dist: Mehsana, Gujarat. PIN: 382715, INDIA.

**8. MARKETING AUTHORIZATION NUMBER**

Will be included after marketing authorization

**9. DATE OF FIRST REGISTRATION / RENEWAL OF THE REGISTRATION**

Will be included after marketing authorization

**10. DATE OF REVISION OF THE TEXT**

Will be included after marketing authorization