

### 1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

#### 1. NAME OF THE MEDICINAL PRODUCT

**PRODUCT NAME:** Diclofenac sodium 1%, Linseed oil 3%, Methyl salicylate 10% and Menthol 5% w/w

**BRAND NAME:** Diclosal Plus Cream

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tube contains

Diclofenac sodium.....1%  
Linseed oil.....3%  
Methyl salicylate.....10%  
Menthol.....5%  
Excipients.....q.s

For complete list of excipients refer section 6.1.

#### 3. PHARMACEUTICAL FORM:

Cream

A clear, transparent, colorless cream

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

(Diclofenac Sodium, Linseed Oil, Methyl Salicylate & Menthol Gel) is indicated for the treatment of sprains, strains, bruises, soft tissue rheumatism. Diclofenac Sodium, Linseed Oil, Methyl Salicylate & Menthol Gel is a warming non-staining, quick relief gel indicated in aches and pains of joints and muscles associated with arthritis, backaches, rheumatism, fibrositis, lumbago, sciatica, stiff neck, as a home treatment for stiff nose, aching feet, tennis elbow, rheumatic pain, bruises and chilblains.

##### 4.2 Posology and method of administration:

Direction: Approximately one-inch band of Diclosal plus cream (Diclofenac Sodium, Linseed Oil, Methyl Salicylate & Menthol Gel) should be applied to the affected site three to four times daily with rubbing till the film disappears.

Route: For external application only.

Dosage:

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Gently rub a small quantity of the gel on the intact skin, on or around the painful/swollen area, till the gel disappears.

Usually a blob equivalent to about 3 cm should suffice. The quantity however would vary depending on the size of the affected area. Do not cover the applied areas with a bandage, etc. Apply 3-4 times a day or as directed by your doctor.

Do not apply the gel on cuts, open wounds or diseased skin area.

Be careful not to apply the gel on or near the eyes, nose, mouth, genital or anal areas. If the gel does come in contact with any of these areas rinse with plenty of clean water.

Obtain your doctor's consent before using the gel in case you are pregnant or breast feeding.

#### **4.3 Contraindications:**

(Diclofenac Sodium, Linseed Oil, Methyl Salicylate & Menthol Gel) is contraindicated in patients who are hypersensitive to any of the component of gel formulation. Diclofenac Sodium, Linseed Oil, Methyl Salicylate & Menthol Gel should not be applied to patients who have experienced asthma, acute rhinitis or urticaria, allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients.

The use of (Diclofenac Sodium, Linseed Oil, Methyl Salicylate & Menthol Gel) is contraindicated during the last trimester of pregnancy.

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

Patients should avoid taking a hot bath or shower just before or after applying gel, as it can enhance the burning sensation. It should not be allowed to come into contact with the eyes or mucous membranes. Tight bandages should not be applied on top of gel. Hands should be washed immediately after application of gel unless hands and fingers are being treated. As with other NSAIDs, anaphylactoid reactions may occur in patients without prior exposure to diclofenac. Diclofenac sodium should be applied with caution to patients with the aspirin triad. The triad typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs. Diclofenac should not be applied to skin wounds, infections or exfoliative dermatitis. This product should be used with caution in patients with a history of active gastrointestinal ulceration or bleeding, or reduced heart, liver or renal function, since isolated cases of systemic adverse reactions consisting of renal affection, has been reported with topically administered antiphlogistic.

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It is known that NSAIDs can interfere with platelet function. Although the likelihood of systemic side effects is very low, caution should be used in patients with intracranial hemorrhage and bleeding diathesis.

Direct sunlight, including solarium, should be avoided during treatment. If sensitivity skin reactions occur, discontinue use.

#### **4.5 Drug Interactions**

Systemic absorption of diclofenac from topical application is very low and no drug interactions during treatment with Diclosal plus cream (Diclofenac Sodium, Linseed Oil, Methyl Salicylate & Menthol Gel) have been reported, there have been reports that topical salicylates may potentiate the anticoagulant effects of warfarin. Menthol has also been reported to interact with warfarin (when taken orally), decreasing its effectiveness.

#### **4.6 Pregnancy & Lactation**

There is no, or inadequate evidence of safety in human pregnancy or lactation. As a precautionary measure, Diclosal plus cream (Diclofenac Sodium, Linseed Oil, Methyl Salicylate & Menthol Gel) should only be used during pregnancy or lactation when there is no safer alternative.

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

Not applicable.

#### **4.8 Adverse Effects**

Occasionally local side effects such as skin rash, itching and reddening may be observed. In clinical studies, localized dermal side effects such as contact dermatitis, exfoliation, dry skin, and rash were found in patients treated with Diclosal plus cream (Diclofenac Sodium, Linseed Oil, Methyl Salicylate & Menthol Gel) at a higher incidence than in those with placebo.

If severe dermal reactions occur, treatment with Diclosal plus cream (Diclofenac Sodium, Linseed Oil, Methyl Salicylate & Menthol Gel) may be interrupted until the condition subsides.

#### **4.9 Overdose**

Signs and symptoms

The low systemic absorption of topical Diclofenac renders overdosage extremely unlikely. In the event of accidental ingestion, resulting in significant systemic side-effects, general therapeutic

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measures normally adopted to treat poisoning with non-steroidal anti-inflammatory drugs should be used.

#### Treatment

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

### **5. PHARMACOLOGICAL PROPERTIES:**

#### **5.1 Pharmacodynamic properties**

Topical antirheumatics and analgesics.

ATC Code: MA01AB55

Mechanism of Action:

Diclofenac works by blocking the effect of chemicals called cyclo-oxygenase (COX) enzymes. These enzymes help to make other chemicals in the body, called prostaglandins. Some prostaglandins are produced at sites of injury or damage causing pain and inflammation. By blocking the effect of COX enzymes, fewer prostaglandins are produced, which means pain and inflammation are eased. The linseed oil helps in the penetration of the diclofenac through the skin. Methyl salicylate also acts as an analgesic and menthol gives relief due to its cooling effect.

#### **5.2 Pharmacokinetic properties**

When applied topically, diclofenac sodium, methyl salicylate linseed oil and menthol are absorbed and penetrate into the subcutaneous tissue, muscle tissue and joint.

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

Not applicable

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Diclofenac Sodium BP

Methyl Salicylate

Menthol BP

Linseed Oil BP

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Glycerol Monostearate BP  
Cetostearyl Alcohol BP  
Butylated Hydroxy Anisol BP  
White Beewax  
Light LiquidParafin BP  
Sodium Lauryl Sulphate  
Carbopol BP  
Disodium EDTA BP  
Propylene Glycol BP  
Benzyl Alcohol BP  
Freshly Prepared Purified Water

## **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.

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

The cream is filled into aluminium tube and packed in inner carton along with leaflet. Pack sizes available is 1 X 30g

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

No special requirements.

## **7. APPLICANT**

### **Name of the Applicant:**

Business Address:  
Plot 6, New Makun City,  
Along Lagos/Ibadan expressway,  
K/m 53/55 Sagamu.  
Ogun State,  
NIGERIA

Manufactured by:

SAGAR VITACEUTICALS NIGERIA LIMITED.

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**8. WHO PREQUALIFICATION REFERENCE NUMBER**

Not applicable

**9. DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION**

Not applicable

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

Not applicable

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