Product Information

Summary of Product Characteristics (SmPC):

1. **NAME OF THE MEDICINAL PRODUCT:**

   ZORTAFEN CREAM (Diclofenac Diethylamine, Methyl Salicylate & Menthol CREAM)

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION:**

   Composition:

   - Diclofenac Diethylamine BP (1.16 % w/w) (ACT)
   - Eq. to Diclofenac Sodium BP (1.00 % w/w) (ACT)
   - Methyl Salicylate BP (10.00 % w/w) (ACT)
   - Menthol BP (5.00 % w/w) (ACT)
   - CREAM Base (Q.S.)

3. **PHARMACEUTICAL FORM:** TOPICAL CREAM

4. **CLINICAL PARTICULARS:**

Therapeutic Indications

ZORTAFEN CREAM (Diclofenac Diethylamine,Methyl Salicylate & Menthol CREAM) is indicated for the treatment of sprains, strains, bruises, soft tissue rheumatism. Diclofenac Sodium, Methyl Salicylate & Menthol CREAMis a warming non-staining, quick relief CREAM 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 **ZORTAFEN CREAM** (**Diclofenac Diethylamine, , Methyl Salicylate & Menthol CREAM)** should be applied to the affected site three to four times daily with rubbing till the film disappears.

Route: For external application only.

Dosage:

Gently rub a small quantity of the CREAM on the intact skin, on or around the painful/swollen area, till the CREAM 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 CREAM on cuts, open wounds or diseased skin area.

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

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

4.3 Contraindications

ZORTAFEN CREAM (Diclofenac Diethylamine, , Methyl Salicylate & Menthol CREAM) is contraindicated in patients who are hypersensitive to any of the component of CREAM formulation. Diclofenac Sodium, , Methyl Salicylate & Menthol CREAMshould 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 **KRISHAT RELIEF CREAM (Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate & Menthol CREAM)** is contraindicated during the last trimester of pregnancy.

4.4 Special warnings and precautions for use

Patients should avoid taking a hot bath or shower just before or after applying CREAM, 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 CREAM. Hands should be washed immediately after application of CREAM 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 antiphlogistics.

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 haemorrhage and blooding diathesis.

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

4.5 Interaction with other medicinal products and other forms of interaction

Systemic absorption of diclofenac from topical application is very low and no drug interactions during treatment with **ZORTAFEN CREAM** (Diclofenac Diethylamine, , Methyl Salicylate & Menthol CREAM)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 Fertility, pregnancy and lactation

There is no, or inadequate evidence of safety in human pregnancy or lactation. As a precautionary measure, **ZORTAFEN CREAM** (Diclofenac Diethylamine, Methyl Salicylate & Menthol CREAM)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 Undesirable effects

Occasionally local side effects such as skin rash, itching and reddening may be observed. In clinical studies, localized derminal side effects such as contact dermatitis, exfoliation, dry skin, and rash were found in patients treated with **ZORTAFEN CREAM**(Diclofenac Diethylamine, , Methyl Salicylate & Menthol CREAM)at a higher incidence than in those with placebo.

If severe dermal reactions occur, treatment with **ZORTAFEN CREAM**(Diclofenac Diethylamine, , Methyl Salicylate & Menthol CREAM)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 measures normally adopted to treat poisoning with non-steroidal anti-inflammatory drugs should be used.

Treatment

Management of overdosage with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from diclofenac 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 haemoper fusion are probably.

5. Pharmacological properties

5.1 **Pharmacodynamic properties**

Pharmacotherapeutic group: 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 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 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

Carbomer 934 Disodium Edetate

Butylated Hydroxy Toluene

Propylene Glycol

Benzyl Alcohol

Isopropyl Alcohol

Polyoxyl 40 Hydrogenated Castor Oil

Triethanolamine

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 lami tube and packed in inner carton along with leaflet. Pack sizes available is 30g.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

Emzor Pharmaceutical Industries Limited

Manufacturing Plant

Emzor Pharmaceutical, Shagamu, Ogun State.

1. Marketing authorisation number(s)

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2. Date of first authorisation/renewal of the authorisation

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3. Date of revision of the text
