# SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

## 1. NAME OF THE MEDICINAL PRODUCT

**DOFEC PLUS GEL** (Methyl Salicylate, Levomenthol, Virgin Linseed Oil and Diclofenac Diethylamine Gel)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Methyl Salicylate BP……………….. 10% w/w
Levomenthol BP…………………….5% w/w
Virgin Linseed Oil BP……………….3 % w/w
Diclofenac Diethylamine BP:………..1.16 % w/w
equivalent to Diclofenac Sodium:……1% w/w
Benzyl Alcohol BP (As Preservative): 1 % w/w
For the full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Gel
A white colour gel

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic Indications:

DOFEC PLUS GEL is indicated for the treatment of sprains, strains, bruises, soft tissue rheumatism. Diclofenac Sodium, Linseed Oil, Methyl Salicylate & Menthol Gelis 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:

*Posology*

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.

*Method of administration*

Direction: Approximately one-inch band of DOFEC PLUS GEL should be applied to the affected site three to four times daily with rubbing till the film disappears.
*Route*: For external application only.

### 4.3 Contraindication:

DOFEC PLUS 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 notbe 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 DOFEC PLUS GEL 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 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 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 DOFEC PLUS 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 and Lactation:**
There is no, or inadequate evidence of safety in human pregnancy or lactation. As a precautionary measure, DOFEC PLUS 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 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 DOFEC PLUS GEL at a higher incidence than in those with placebo.
If severe dermal reactions occur, treatment with DOFEC PLUS 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 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 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:

Benzyl Alcohol
Carbomer-934
Propylene Glycol
Cresmer RH 40
Butylated Hydroxytoluene
Citric Acid Monohydrate
Iso Propyl Alcohol
Disodium Edetate
Diethanolamine LR Grade
Purified Water

### 6.2 Incompatibilities:

Not applicable.

### 6.3 Shelf Life:

36 Months

### 6.4 Special Precautions for Storage:

Store below $30^0$C. Protect from light. Do not freeze.

**6.5 Nature and Contents of Container:**
**Primary Packing:** 20 g, 30 g & 50 g Lami tube
**Secondary Packing:** Such 1 tube is packed in a printed carton along with pack insert.

## 7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)
08202/10041/NMR/2022

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/12/2022

## 10. DATE OF REVISION OF THE TEXT

07/07/2023

## 11. REFERENCES