



## Summary of Product Characteristics (SmPC)

### CHAKAPAIN GEL

Diclofenac, Linseed oil, Capsaicin & Menthol Gel

## 1.4 PRODUCT INFORMATION

### 1.4.1 Summary of Product Characteristics (SmPC)

#### 1. Name of the Medicinal Product

##### CHAKAPAIN GEL

Diclofenac, Linseed oil, Capsaicin & Menthol Gel

#### 2. Qualitative and Quantitative Composition

##### Composition:

Diclofenac Diethylamine BP....1.16% w/w

Equivalent to Diclofenac Sodium ..... 1.00% w/w

Linseed Oil BP ..... 3.00% w/w

Capsaicin USP ..... 0.025% w/w

Menthol BP ..... 5.00% w/w

Gel Base.....Q.S.

#### 3. Pharmaceutical Form

Gel


#### 4. Clinical Particulars

##### 4.1 Therapeutic Indications

CHAKAPAIN GEL is indicated for the local symptomatic relief of pain and inflammation occurring due to musculoskeletal disorders (MSDs), sprains and strains, knee pain/arthritis, low back pain, etc.

##### 4.2 Posology and Method of Administration

For topical administration. Adults and children above 14 years of age: Gel should be rubbed gently into the skin. Depending on the area of the affected site, 2 to 4 grams of gel should be applied 3 to 4 times daily. Total dose of diclofenac-containing topical preparation should not exceed 32 gram per day. After application, the hands should be washed unless they are the site being treated. In the treatment of osteoarthritis, therapy should be reviewed after 4 weeks while in other indications, it is recommended that the treatment be reviewed after 14 days. Or, as prescribed by the physician.

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### 4.3 Contraindications

CHAKAPAIN GEL is contraindicated in the following:

- Known or suspected hypersensitivity to diclofenac or aspirin or other NSAIDs, linseed oil, menthol, capsaicin or to any other component of the formulation.
- Concomitant use of oral diclofenac or other NSAIDs/aspirin.
- In patients with aspirin or salicylate idiosyncrasy.
- Patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs.
- In the setting of coronary artery bypass graft (CABG) surgery.

### 4.4 Special Warnings and Precautions for Use

The possibility of systemic adverse events from application of this topical therapy cannot be excluded if this product is used on large areas of skin and over a prolonged period of time.

**Concomitant Use of Oral NSAIDs:** Concomitant use of oral NSAIDs with DICLOTALFORTE Gel should be best avoided, as incidence of adverse effects of NSAIDs may increase, particularly systemic side effects.

**Skin Reactions:** NSAIDs, including diclofenac, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations, and the use of the drug should be discontinued at the first appearance of skin rash or any other signs of hypersensitivity.

**Sun Exposure:** Patients should minimize or avoid exposure to natural or artificial sunlight on treated areas because studies in animals indicated topical diclofenac treatment resulted in an earlier onset of ultraviolet light-induced skin tumors. The potential effects of diclofenac gels on skin response to ultraviolet damage in humans are not known.

#### **Warnings and Precautions of Diclofenac Sodium Topical Gel**

**1. Hepatotoxicity:** Inform patients of warning signs and symptoms of hepatotoxicity. Discontinue if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop.



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**2. Hypertension:** Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure.

**3. Heart Failure and Edema:** Avoid use of CHAKAPAIN GEL in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure.

**4. Renal Toxicity:** Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of CHAKAPAIN GEL in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function.

**5. Anaphylactic Reactions:** Seek emergency help if an anaphylactic reaction occurs.

**6. Exacerbation of Asthma Related to Aspirin Sensitivity:** CHAKAPAIN GEL is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).

**7. Serious Skin Reactions:** Discontinue CHAKAPAIN GEL at first appearance of rash or other signs of hypersensitivity.

**8. Premature Closure of Fetal Ductus Arteriosus:** Avoid use in pregnant women starting at 30 weeks gestation.

**9. Hematologic Toxicity:** Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia.

#### **Precautions**

- FOR EXTERNAL USE ONLY.
- NOT FOR VETERINARY USE.
- Discontinue the treatment if a skin rash develops after applying this product.
- Avoid showering/bathing for at least 1 hour after the application.
- Avoid wearing of clothing or gloves for at least 10 minutes after applying the gel.
- Do not apply gel to open skin injuries/wounds, irritated skin, infections, skin abrasions.
- Avoid contact of gel with eyes and mucous membranes.
- Do not apply external heat and/or occlusive dressings to treated joints.
- Avoid exposure of the treated joint(s) to natural or artificial sunlight.



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- Avoid concomitant use of gel on the treated skin site with other topical products, including sunscreens, cosmetics, lotions, moisturizers, insect repellants, or other topical medications.
- Should not be co-administered with other products containing diclofenac.
- Convulsions have been reported rarely with methyl salicylate, thus, use of this product should be avoided in such cases.

#### 4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Since systemic absorption of diclofenac from topical application of the gel is very low, drug interactions are very unlikely. The following drug interactions have been observed rarely.

**Oral NSAIDs:** Concomitant administration of CHAKAPAIN GEL with oral diclofenac or other NSAIDs/aspirin is generally not recommended because of the potential for increased risk of GI events including ulceration, bleeding, and perforation.

**Anticoagulants:** Concomitant use of anticoagulants and diclofenac has a risk of serious GI bleeding higher than use of either drug alone.

#### 4.6 Pregnancy and Lactation

##### Pregnant Women

The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. But, due to lack of safety data in pregnant women and fetus, use of diclofenac containing topical preparations are not indicated during pregnancy. This applies in particular to the third trimester of pregnancy, owing to the possibility of uterine inertia and/or premature closure of the ductus arteriosus.

##### Lactating Women

Like other non-steroidal anti-inflammatory drugs (NSAIDs), diclofenac passes into breast milk in small amounts. However, at therapeutic doses no effects on the breast-feeding infants are anticipated. Because of a lack of controlled studies in lactating women, this product should be used during lactation only if clearly needed and under medical supervision. Even if it is used, gel should neither be applied on the breasts of nursing mothers nor elsewhere on large areas of the skin or for a prolonged period of time.



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#### Paediatric Patients

Safety and effectiveness of CHAKAPAIN GEL in children below 14 years of age have not been established. Geriatric Patients No overall differences in effectiveness or safety have been observed between the elderly population and younger subjects, but greater sensitivity to the effect of NSAIDs in some older individuals cannot be ruled out.

#### 4.7 Effects on Ability to Drive and Use Machines

Topical application of CHAKAPAIN GEL has no influence on the ability to drive and use machines.

#### 4.8 Undesirable Effects

**Local:** This preparation is usually well tolerated. Commonly/occasionally reported adverse reactions are application site reactions, including skin irritation, rash, dermatitis, pruritus, erythema, paresthesia, vesicles, papules, redness or swelling, burning or stinging sensation. Skin photosensitivity, desquamation, discolouration and bullous or vesicular eruptions have been reported in isolated cases. Patients should be warned against excessive exposure to sunlight in order to reduce the incidence of photosensitivity. This product may cause hypersensitivity/allergic reactions in some individuals with sensitive skin. If hypersensitivity/allergic reactions develop or if any of the above effects/reactions persist or worsen, discontinue use of the drug and seek immediate medical attention.

**General:** The possibility of systemic adverse events from topical application of this product cannot be excluded if the preparation is used (either accidentally or deliberately) on large areas of skin and over a prolonged period which is usually not recommended. Asthma has been reported, albeit rarely, in patients using topical NSAID preparations.

#### 4.9 Overdose

**Symptoms:** Overdose with CHAKAPAIN GEL is very unlikely, due to its low systemic absorption. No event of accidental ingestion has been reported in the literature. However, as it contains diclofenac, undesirable effects similar to those observed following an overdose of diclofenac tablets can be expected if it is inadvertently ingested. Symptoms following acute oral NSAID overdose are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are



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generally reversible with supportive care. GI bleeding, hypertension, acute renal failure, respiratory depression, and coma may occur. Anaphylactic reactions have been reported with therapeutic intake of NSAIDs, and may occur after an overdose. When accidentally ingested by oral route large doses of linseed oil may cause loose stools and diarrhea. Salicylate intoxication can occur after ingestion or topical application of methyl salicylate. Mild chronic salicylate intoxication or salicylism usually occurs only after repeated use of large doses. Salicylism can also occur following excessive topical application of salicylates. Ingestion of significant quantities of menthol is reported to cause symptoms such as severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness, and coma. In overdose, capsaicin can cause burning or stinging pain to the skin and, if ingested in large amounts by adults or small amounts by children, can produce nausea, vomiting, abdominal pain, and burning diarrhea.

**Treatment:** Management of overdose essentially consists of supportive and symptomatic measures. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, GI irritation, and respiratory depression. Gastric decontamination and the use of activated charcoal should be considered, especially within a short time of ingestion. 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

#### Diclofenac


Diclofenac, an NSAID, exhibits anti-inflammatory and anti-nociceptive/analgesic effects. Linseed Oil Linseed oil (flaxseed oil) has anti-inflammatory, analgesic, antioxidant, and anesthetic properties.

#### Menthol

Menthol has rubefacient effect. When applied gently on the skin, menthol acts as an anti-pruritic agent and creates a feeling of coolness, and a mild local anesthetic effect. Menthol has good soothing effect. Menthol also acts as a penetration enhancer, increasing the penetration of topically-applied drugs and providing a faster onset of action.

#### Capsaicin

Capsaicin (found in chili peppers) produces a burning sensation when applied locally. Capsaicin is used to treat minor aches and pains of the muscles and joints (e.g., arthritis, backache, sprains). Capsaicin is also useful in diabetic nerve pain (neuropathy).

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## 5.2 Pharmacokinetic Properties

### Diclofenac

When applied locally, diclofenac sodium is absorbed through the skin. In healthy volunteers, approximately 6% of the applied dose is absorbed as determined by urinary excretion of diclofenac and its hydroxylated metabolites. Following local application of gel, diclofenac penetrates into the inflamed areas. After topical administration of gel to hand and knee joints, diclofenac can be measured in plasma, synovial tissue, and synovial fluid. Maximum plasma concentration of diclofenac is about 100 times lower than following oral administration of diclofenac.

### Linseed Oil

Pharmacokinetic properties of linseed oil after topical application are not known.

### Menthol

After absorption, menthol is excreted in the urine and bile as a glucuronide.

### Capsaicin

No pharmacokinetic data is available for topical use of capsaicin.

## 6. Pharmaceutical Particulars

### 6.1 List of Excipients

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### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf Life

36 months

### 6.4 Special Precautions for Storage


Do not store above 30 °C, Protect from light and moisture.

### 6.5 Nature and Contents of Container

1 x 30 gm

### 6.6 Special Precautions for Disposal

Any unused medicinal products or waste material should be disposed of in accordance with local requirements.

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**7. APPLICANT/SUPPLIER**

**CLAROID PHARMACEUTICAL LTD.**

Survey No. 217/P Opp. Gurukul English Medium School Kamod, Satpanth Mandir  
Pirana Rd, TA, Ahmedabad- 382425, Gujarat, India.

**8. WHO PREQUALIFICATION REFERENCE NUMBER**

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

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**10. Date of Revision of the Text**

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