Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

STEDNAC GEL Roll-on

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of STEDNAC GEL contains:
- Aceclofenac BP: 1.5% w/w (15 mg)
- Methyl Salicylate BP: 10.0% w/w (100 mg)
- Menthol BP: 5.0% w/w (50 mg)
- Linseed Oil BP (Containing alpha-linolenic acid):
3.0% w/w (30 mg)
- For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical Gel Roll-on.
A smooth, homogeneous white to off-white gel with a characteristic pleasant aromatic odor of menthol and methyl salicylate.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

STEDNAC GEL is indicated for the local symptomatic relief of pain and inflammation associated with:
- Musculoskeletal disorders including sprains, strains, tendinitis, tenosynovitis, bursitis, and fibrositis.
- Osteoarthritis of superficial joints (such as the knee and hands).
- Low back pain, lumbago, and sports-related soft tissue injuries.

4.2 Posology and method of administration

Posology:
- *Adults and Elderly:* Apply a thin layer to the affected area 2 to 3 times daily depending on the size of the painful site.
- *Pediatric population:* Not recommended for use in children under 12 years of age due to insufficient data on safety and efficacy.

Method of administration:
- For cutaneous use only. Roll directly onto clean, dry skin over the painful site and gently massage until absorbed.

• Wash hands thoroughly after application unless hands are the treated area.

Treatment should not exceed 14 consecutive days without medical review.

4.3 Contraindications

• Hypersensitivity to aceclofenac, methyl salicylate, menthol, linseed oil, or any of the excipients.

• Patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs).

• Application to broken, diseased, infected, or open skin surfaces, wounds, or eczematous lesions.

• Third trimester of pregnancy.

4.4 Special warnings and precautions for use

• Discontinue immediately if a skin rash or irritation develops after application.

• Avoid contact with eyes, mucous membranes, or sensitive skin surfaces. In case of accidental contact, rinse thoroughly with clean running water.

• Do not apply under occlusive dressings or airtight bandages.

• Use with caution in patients with a history of active peptic ulceration, renal hepatic insufficiency, or hemorrhagic diathesis, although systemic absorption is low.

• Concurrent use of oral NSAIDs should be carefully monitored to minimize potential cumulative systemic adverse reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Systemic absorption of aceclofenac and other components following topical administration is very low, making systemic drug interactions highly unlikely. However, caution should be exercised if used concurrently with oral NSAIDs, anticoagulants (e.g., warfarin), or antiplatelet agents due to a theoretical risk of additive effects.

4.6 Fertility, pregnancy and lactation

Pregnancy: Systemic concentrations are lower after topical administration compared to oral formulations. However, use is not recommended during the first and second trimesters unless essential, and is strictly contraindicated during the third trimester due to risks of premature closure of the ductus arteriosus and uterine inertia.

Lactation: It is not known whether topical aceclofenac or its metabolites are excreted in human milk. A risk to the newborn/infant cannot be excluded. Use during breastfeeding should only be considered if the expected benefit outweighs the potential risk, and it must not be applied to the breasts.

4.7 Effects on ability to drive and use machines

STEDNAC GEL has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000).

• *Skin and subcutaneous tissue disorders:* Common: Mild erythema, localized skin irritation, pruritus, dermatitis. Rare: Photosensitivity reactions, contact dermatitis. Very rare: Severe bullous eruptions (including
Stevens-Johnson syndrome and toxic epidermal necrolysis).

• *Immune system disorders:* Very rare: Hypersensitivity reactions including angioedema and anaphylactic shock.

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. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9 Overdose

Given the topical mode of delivery, systemic overdose is highly improbable. If accidental ingestion occurs, standard symptomatic and supportive treatment protocols for NSAID toxicity should be initiated immediately.

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: M02AA.

• **Aceclofenac:** An NSAID with potent anti-inflammatory and analgesic effects acting primarily through the inhibition of the cyclooxygenase (COX) enzyme, thereby blocking prostaglandin synthesis.
• **Methyl Salicylate:** Acts as a counter-irritant. It induces local vasodilation and cutaneous warmth, effectively masking deep-seated structural pain signals.
• **Menthol:** Stimulates cold-sensitive receptors in the skin, producing a cooling sensation followed by a mild analgesic effect.
• **Linseed Oil:** Rich in essential fatty acids (specifically alpha-linolenic acid), contributing to the structural stabilization of cell membranes and offering ancillary anti-inflammatory action.

5.2 Pharmacokinetic properties

Following topical application via roll-on, the active elements penetrate the skin barriers locally to reach therapeutic concentrations in underlying inflamed joints, muscles, and synovial fluids. Systemic plasma concentrations of aceclofenac remain exceptionally low (<5%) compared to equivalent therapeutic oral doses, minimizing systemic clear path clearances and metabolism pathways.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, and carcinogenic potential. Local tolerance studies indicate the formulation is well-tolerated on intact skin surfaces with low irritant potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol, Ethanol, Carbomer, Triethanolamine, Polyoxyl 40 hydrogenated castor oil, Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months (3 years) when stored in original unopened packaging.

6.4 Special precautions for storage

Store below 30°C. Protect from direct sunlight and heat. Do not freeze. Keep the container tightly capped when not in use.

6.5 Nature and contents of container

High-Density Polyethylene (HDPE) bottle equipped with a roller-ball applicator assembly and a secure polypropylene screw-cap cover. Pack size: 50 ml and 100 ml configurations.

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER

Stednac Pharmaceuticals
Ltd. Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER(S)

H2024/CTD11105/24818

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2024 October 24

10. DATE OF REVISION OF THE TEXT

02/09/2026