SYNFLEX® Gel

(Naproxen Sodium 10% w/w)

سنفلکس جل

DESCRIPTION
Synflex gel belongs to topical drugs for treatment of joint and muscle pains – non-steroidal anti-inflammatory drugs for topical use.

COMPOSITION
Each gram contains:
Naproxen Sodium (USP) ……10% w/w

THERAPEUTIC INDICATIONS
• Synflex gel is indicated in adults and children above 12 years for topical treatment of pain in musculoskeletal disorders such as myalgia, backache, stiff neck, bursitis, tendinitis, tenosynovitis, periarthritis, muscular sprains, contusions, hematoma.
• Coadjuvant to orthopaedic and rehabilitation therapies.

DOSAGE AND ADMINISTRATION
Apply Synflex Gel 10% on the affected area two times a day and lightly massage to until completely absorbed.
Maximum duration of use should not exceed 7 days.

CONTRAINDICATIONS
• Hypersensitivity to the active substance or any of the excipients.
• Third trimester of pregnancy.

WARNINGS AND PRECAUTIONS
• Avoid using the gel on eyes, mucous membranes, wounds and/or skin lesions.
• Blood concentrations reached by active substance absorbed through the skin are not such as to expose to risks of undesirable effects or make warnings concerning the systemic administration of the drug applicable.
• However, use of Naproxen Sodium Gel is not recommended in patients presenting allergic reactions to acetylsalicylic acid and/or other NSAIDs and is also not recommended in patients with history of allergic occurrences or allergic events in progress.
• To prevent any phenomena of hypersensitivity or photosensitivity, avoid exposure to direct sunlight, including solarium, during the treatment and for 2 weeks afterwards.
• The use of the product should be discontinued if the patients present any rash or irritation of the skin.
• Naproxen Sodium Gel has no influence on the ability to drive and use machines.

DRUG INTERACTIONS
No interaction data is available. The product is systemically little-absorbed and therefore, though possible, forms of interaction with other medicinal products are unlikely.

USE IN SPECIAL POPULATION
Fertility, pregnancy and lactation
The risk of harmful effects to the fetus and/or the child is not excluded. Therefore Naproxen Sodium Gel 10% during pregnancy and/or breastfeeding should be used on medical advice and when strictly necessary. Naproxen Sodium 10% gel is contraindicated during the third trimester of pregnancy.
Paediatric population
Naproxen Sodium gel is not recommended for use in children below 12 years. The safety and efficacy of Naproxen Sodium Gel 10% in children under 12 years have not yet been established. No data is available.

ADVERSE REACTION
The frequency of undesirable effect is defined as follows: Very common (1/10), 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), Not known (cannot be estimated from the available data).
Skin and subcutaneous tissue disorders: Erythema, Pruritus, Skin irritation, Skin burning sensation, Dermatitis contact, Bullous eruption, Photosensitivity reaction (Frequency not known).
With some non-steroid anti-inflammatory dermal or trans-dermal products, derived from propionic acid, adverse skin reactions have been noted. The prolonged use of products for topical administration may cause hypersensitivity phenomena. In such cases the treatment should be discontinued and a suitable alternative therapy instituted.
Immune system disorders: Sensitization (Frequency not known)
General disorders and administration site conditions: Sensation of warmth (Frequency not known)

OVERDOSE
No case of overdose is known to have been reported.

CLINICAL PHARMACOLOGY
Pharmacodynamics
Naproxen Sodium gel belongs to topical drugs for treatment of joint and muscle pains – non-steroidal anti-inflammatory drugs for topical use. Naproxen Sodium is a non-steroidal anti-inflammatory drug with analgesic and anti-exudative properties.
Most of the pharmacological effects of Naproxen Sodium, as with other NSAIDs, are mediated by inhibiting cyclo-oxygenase (COX) (a critical enzyme in the biosynthetic pathway of prostaglandins) with consequent suppression of prostaglandin biosynthesis. Naproxen Sodium is known to inhibit COX-1 and COX-2 demonstrating equal selectivity for both isoform as indicated by COX-2/COX-1 IC50 ratio of 0.88.
The inhibited synthesis of prostaglandins accounts for the favorable effect on inflammation and pain.

Pharmacokinetics
Following repeated doses of Naproxen Sodium gel administered topically, the peak systemic exposition is known to be approx. 100-times lower compared to the maximum exposition observed after Naproxen Sodium 200mg administered orally.
In particular, the mean peak plasma concentration induced by Naproxen Sodium gel applied twice daily for 7 days is known to be approx. 0.5 µg/ml, and the mean area under the curve (AUC) is known to be equal to 5.4 µg/ml*h.

STABILITY
See expiry on the pack.

PACK
Synflex Gel is supplied in following dosage form, strength and pack size:
Gel 10% w/w 50g

INSTRUCTIONS
Keep all medicines out of the reach of children.
Protect from light, heat and moisture.
Store below 30°C.

To be sold on prescription of a registered medical practitioner only.

FOR EXTERNAL USE ONLY

ہدایات:
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
روشنی، گرمی اور نمی سے محفوظ رکھیں۔
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کی جائے۔

صرف بیرونی استعمال کے لیے۔

Manufactured by:
Seatle (Private) Limited
45-Km Multan Road, Lahore-Pakistan.
Martin Dow