

NIDOL[®] GEL

Nimesulide Transdermal Gel 2 %

**PRESCRIPTION DRUG ONLY
FOR EXTERNAL USE ONLY!**

International Non-proprietary Name

Nimesulide

Composition

Active ingredients: each gram of Nidol[®] GEL contains Micronised Nimesulide 20 mg.

Excipients: propylene glycol, triethanolamine, carbomer, polyethylene glycol, methylparaben, propylparaben, edetate disodium, purified water.

Therapeutic Properties

Nidol[®] GEL is a nonsteroidal anti-inflammatory drug (NSAID) which also possesses antiphlogistic and analgesic activities.

Pharmacokinetics

Following topical administration Nimesulide Gel is quickly and well-absorbed by the skin. Peak plasma concentration is reached within 1-2 hours; the drug has a half-life of 4-5 hours.

Indications

Nidol[®] GEL is indicated for symptomatic relief of pain associated with sprains and acute traumatic tendinitis.

Recommended Dosage & Administration

ADULT

Nimesulide 2% gel (usually 3g, corresponding to a line 6-7 cm long) should be applied in a thin layer to the affected area 2-3 times daily and massaged until it is completely absorbed.

CHILDREN under 12 years

Nimesulide 2% gel has not been studied in children. Therefore, safety and efficacy have not been established and the product should not be used in children.

Contraindications

- Known hypersensitivity to nimesulide or to any of the excipients in the gel.
- Use in patients in whom aspirin, or other medical product inhibiting prostaglandin synthesis, induced allergic reactions such as rhinitis, urticaria or bronchospasm.
- Use on broken or denuded skin or in the presence of local infection.
- Simultaneous use with other topical creams.
- Use in children under 12 years.

Side Effects

Side effects possibly related to treatment with Nimesulide Gel have been infrequently reported. The most commonly observed side effects include mild or moderate local irritation, erythema, rash, scaling, pruritus and related local reactions at the application site. Mild but transient skin discolouration and staining of clothing have been noted.

Overdosage

An overdosage of Nimesulide Gel is not very likely to occur due to its topical application, which restricts the effect mainly to the affected site.

Precautions and Warnings

- Nimesulide 2% gel should not be applied to skin wounds or open injuries.
- Nimesulide 2% gel should not be allowed to come into contact with the eyes or mucous membranes; in case of accidental contact, wash immediately with water.
- The product should never be taken by mouth. Hands should be washed after applying the product.
- Nimesulide 2% gel should not be used with occlusive dressings.
- Nimesulide 2% gel is not recommended for use in children under 12 years (see section Contraindications)
- Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration.
- Patients with gastro-intestinal bleeding, active or suspected peptic ulcer, severe renal or hepatic dysfunction, severe coagulation disorders or severe/non controlled heart failure should be treated with caution.

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- To reduce the risk of photosensitivity, patients should be warned against exposure to direct and solarium sunlight.

Since nimesulide 2% gel has not been studied in hypertensive subjects, particular caution should be used when treating patients with known hypersensitivity to other NSAIDs. The possibility of developing hypersensitivity in the course of therapy cannot be excluded.

Since with other topical NSAIDs burning sensation and exceptionally photodermatitis can occur, care should be taken during treatment with nimesulide 2% gel.

If symptoms persist or the condition is aggravated medical advice should be sought.

Use during Pregnancy and Lactation

As the safety of Nimesulide Gel has not yet been established during pregnancy or lactation, its use is not recommended.

Drug Interactions

No drug interactions are known.

Shelf life

3 years

Storage Conditions

Store below 25°C.

KEEP OUT OF REACH OF CHILDREN!

Packaging

Lacquered aluminium collapsible tube containing 30 g Gel.

Each gram contains:

Micronised Nimesulide 20 mg.

Manufactured under license for

EURODRUG LABORATORIES S.A.

Kortrijksesteenweg 214

9830 Sint-Martens-Latem, Belgium.

By Polipharm Co., Ltd.

109 Bangna-Trad Road, Bang Phli District,

Sumut Prakan 10540, Thailand

EURODRUG LABORATORIES S.A.

Kortrijksesteenweg 214
9830 Sint-Martens-Latem
Belgium

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