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.
- Complete or incomplete combination of bronchial asthma, angioedema or urticaria, recurrent nasal polyposis and paranasal sinuses and intolerance to acetylsalicylic acid or other NSAIDs, including anamnesis.
- Dermatoses, damage to the epidermis and skin infections in the area of application.
- Erosive and ulcerative lesions of the gastrointestinal tract in the acute stage, bleeding from the gastrointestinal tract.
- Severe renal and hepatic impairment (creatinine clearance < 30 ml/min).
- Pregnancy and breastfeeding period.
- Children's age up to 12 years.
- Use on broken or denuded skin or in the presence of local infection.
- Simultaneous use with other topical creams.

Side Effects

When used externally, the drug is usually well tolerated.
The adverse events presented below are listed depending on the anatomical and physiological classification and frequency of occurrence. Frequency of occurrence side effects are determined by WHO and have the following gradation: very often (≥1/10), often (≥1/100 and <1/10), infrequently (≥1/1000 and <1/100), rarely (≥1/100) 10000 and <1/1000),very rarely (<1/10000, including isolated cases), not established.
Disorders of the skin and subcutaneous tissues: infrequently - itching, very rarely - urticaria, peeling; transient change in skin color (not requiring discontinuation of the product).
When applying the product to large areas of skin or with long-term use, the development of systemic adverse reactions characteristic of nimesulide is possible: heartburn, nausea, vomiting, diarrhoea, gastralgia, ulceration of the gastrointestinal mucosa, increased activity of “liver” transaminases; headache, dizziness; fluid retention, haematuria; allergic reactions (anaphylactic shock, skin rash); thrombocytopenia, leukopenia, anaemia, agranulocytosis, prolongation of bleeding time.

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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.
- To reduce the risk of photosensitivity, patients should be warned against exposure to direct and solarium sunlight.
- The excipients methylparaben and propylparaben may cause allergic reactions.
- The excipient propylene glycol may irritate the skin.

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
The use of the Nimesulide Gel during pregnancy and breastfeeding is contraindicated.

Drug Interactions
It is possible that nimesulide may interact pharmacokinetically with drugs that compete for binding to plasma proteins. Caution should be exercised when using nimesulide simultaneously with digoxin, phenytoin, lithium preparations, diuretics, cyclosporine, methotrexate, other NSAIDs, antihypertensive and hypoglycemic products.
Before using the gel, you should consult your doctor if you are already using these products or are under medical supervision.

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.

Marketing authorization holder
PharmaTech CJSC
111 Raffi str, Yerevan,
Republic of Armenia

Manufactured by

NIDOL® GEL

Nimesulide Transdermal Gel 2 %

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