**APPROVED**
**Order of Ministry of**
**Health of Ukraine**
**03.11.2016 No. 1166**
**Registration certificate**
**No. UA/7649/01/01**

# INSTRUCTION
## for medical use

## NIMID®

***Composition:***
*active substance:* nimesulide;
1 g of gel contains nimesulide 10 mg;
*excipients:* benzyl alcohol, propylene glycol, Carbomer 940, disodium edetate, sodium hydroxide, flavour Cologne Comp 530, purified water.

**Pharmaceutical form.** Gel for external use.
*Basic physical and chemical properties:* opaque homogeneous light-yellow gel.

**Pharmacotherapeutic group.**
Anti-inflammatory preparations, non-steroids for topical use. ATC code M02A A26.

***Pharmacological properties.***
*Pharmacodynamics.*
Nimesulide is a non-steroidal anti-inflammatory drug (NSAID), a selective cyclooxygenase-2 inhibitor. In terms of anti-inflammatory activity, nimesulide in an equimolar concentration in the initial stage of inflammation is comparable to indomethacin and piroxicam. By inhibiting the synthesis of prostaglandins at the site of inflammation, nimesulide has virtually no effect on the synthesis of regulatory prostaglandins in the wall of the stomach and kidneys. It suppresses the activity of platelet activation factor, α-tumour necrosis factor, proteinases, histamine, and the formation of free oxygen radicals. When used externally, it causes a reduction or disappearance of pain in the application area, including joint pain, reduces morning stiffness and swelling of the joints.
*Pharmacokinetics.*
When applying Nimid® to the skin, gradual transdermal absorption of nimesulide into the subcutaneous tissue and synovial fluid of the joint is observed.

**Clinical characteristics.**
***Indications.***
Topical treatment of pathological conditions of the musculoskeletal system characterized by pain, inflammation and stiffness of movements, such as osteoarthritis, periarthritis, post-traumatic tendinitis, tendosynovitis, muscle strains, heavy physical loads on the joints.

***Contraindications.***
- Hypersensitivity to nimesulide or other components of the drug.
- Pregnancy.
- Dermatitis and skin infections.
- Damage to the epidermis.
- Do not use in patients in whom acetylsalicylic acid or other drugs that inhibit prostaglandin synthesis cause allergic reactions, such as rhinitis, urticaria or bronchospasm.

***Interactions with other medicinal products and other forms of interaction.***

During dermal application of the drug, no interaction with other medical products has been revealed. However, it should be taken into account that if nimesulide reaches the systemic circulation, it may induce the effect and toxicity of many medical agents by displacing them from binding to plasma proteins and thus increasing their free fraction in blood. Therefore, caution should be exercised when prescribing the drug concomitantly with anticoagulants, digoxin, phenytoin, lithium drugs, diuretics, antihypertensive drugs, other NSAIDs, cyclosporine, methotrexate, oral hypoglycemic agents.
With the simultaneous local application of several non-steroidal anti-inflammatory drugs, the development of local irritation in the form of urticaria, skin redness, desquamation is possible.
Glucocorticoids and antirheumatic agents (gold preparations, aminoquinolines) enhance the anti-inflammatory effect of Nimid®.

***Administration details.***
Medical supervision is necessary when prescribing the drug to elderly patients with impaired function of kidneys, liver, with congestive heart failure. In patients with gastroduodenal bleeding, active ulcers or severe blood clotting disorders, the drug should be used under close medical supervision.
Do not use simultaneously with other topical medications.
It is recommended to apply the gel only on intact skin, avoiding contact with open wounds. Avoid contact with eyes and cutaneous membranes. Do not apply under airtight dressing.
To reduce the risk of side effects, it is necessary to use the minimum effective dose with the shortest duration of the treatment course. If the patient's condition does not improve, the doctor should be consulted for further treatment.
Do not use in patients with known hypersensitivity to NSAIDs. In case of hypersensitivity reactions, the treatment should be discontinued.
During the treatment period, the development of photosensitivity reactions is possible. To reduce the risk of photosensitivity, patients should avoid UV exposure and tanning beds.
The product contains propylene glycol which may cause skin irritation.

*Use during pregnancy or breastfeeding.*
Pregnancy.
There are no clinical data on the use of Nimid® during pregnancy. Even if the systemic exposure is lower compared to oral administration, it is not known whether the systemic exposure of Nimid® after topical application can be harmful to the embryo/fetus.
During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors, including Nimid®, can cause cardiopulmonary and renal toxicity in the fetus. At the end of pregnancy, both mother and child may experience prolonged bleeding, and contractions may be prolonged. Therefore, Nimid® is contraindicated during pregnancy (see "Contraindications" section).
Breastfeeding.
Do not use.

*Effects on ability to drive and use machines.*
The drug has no effect.

***Posology and administration.***
Use topically in adults. Before applying the gel, the surface of the skin should be washed and dried. Apply a strip of gel approximately 3 cm long to painful areas in a thin layer and rub gently; the frequency of application is 3–4 times a day.
The duration of therapy is determined individually depending on its efficacy and is no more than 4 weeks.

***Children.***
Do not use in children.

***Overdose.***

When applying the gel on large skin areas or in case of exceeding the recommended dose, systemic adverse effects, typical for nimesulide and other non-steroidal anti-inflammatory drugs, are possible: dyspepsia, headache, dizziness, epigastric pain.
*Treatment:* dose reduction or discontinuation of the drug. The treatment is symptomatic.

***Adverse reactions.***
*Skin disorders:* local skin irritation of mild and moderate severity, such as erythema, rash, desquamation, itching, allergic reactions.
*Immune system disorders:* hypersensitivity reactions including anaphylactic reactions such as Quincke's oedema, vasomotor rhinitis, asthma panting and bronchospasm.

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. Medical and pharmaceutical workers, as well as patients or their legal representatives are asked to report any suspected adverse reactions and lack of effectiveness of the medicinal product through the Pharmacovigilance Automated Information System at: https://aisf.dec.gov.ua.

***Shelf life.*** 3 years.

**Storage conditions.**
Store at the temperature not more than 25°C in the original package.
Do not freeze.
Keep out of reach of children.

**Package.**
30 g or 100 g in a tube. 1 tube in a carton package.

**Conditions of supply.**
Without prescription.

**Manufacturer.**
KUSUM HEALTHCARE PVT LTD.

**Location of manufacturer and its address of business activity.**
SP-289 (A), RIICO Industrial area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan), India.

**Date of last revision.** 09.10.2024