

PATIENT INFORMATION LEAFLET

NIMEKSIL 1% Gel

For external use.

- **Active substance:** Each gram of gel contains 10 mg of nimesulide.
- **Excipients:** Macrogol 400, propylene glycol, sepineo P 600, ethanole, pure water.

Please read this leaflet carefully before you start to take your medicine, because it contains important information for you.

- *Keep the leaflet in a safe place because you may want to read it again.*
- *If you have any other questions, or if there is something you do not understand, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Never give it to someone else.*
- *If you go to hospital while you are taking this medicine, you need to inform your doctor about it.*
- *Follow the instructions in the leaflet exactly. Do not use **higher or lower** dosage of recommended one.*

What is in this leaflet:

1. *What NIMEKSIL is and what it is used for?*
2. *What you need to know before you take NIMEKSIL.*
3. *How to take NIMEKSIL?*
4. *What are possible side effects?*
5. *How to store NIMEKSIL?*

1. What NIMEKSIL is and what it is used for?

- NIMEKSIL is gel form a medicine that contains nimesulide as active substance.
- NIMEKSIL belongs to a group of drugs called topically used non-steroidal anti-inflammatory preparations.
- NIMEKSIL is supplied in aluminum tubes and cardboard boxes containing 30 grams of gel.
- NIMEKSIL use for the treatment of soft tissue rheumatic diseases, soft tissue disorders such as crush and sprain, musculoskeletal disorders manifested by pain, inflammation, and muscle tension as pain relief and anti-inflammatory.

2. Things to consider before you start to take NIMEKSIL.

DO NOT USE NIMEKSIL in the following situations

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- If you are allergic to nimesulide or any of the other ingredients of this medicine, you do not use NIMEKSIL.
- If drugs containing acetylsalicylic acid (aspirin, etc.) that stimulate allergic reactions and inhibit prostaglandin synthesis or other drugs included in the group of drugs called nonsteroidal antiinflammatory drugs cause to this diseases like asthma, allergic runny nose (rhinitis), skin rash and itching (urticaria), swelling of soft tissues such as eyelids, external reproductive organs, lips and tongue (angioedema) and the formation of meat in the nose, you do not use NIMEKSIL.
- If your skin has local infection and injury, you do not use NIMEKSIL.
- You do not use NIMEKSIL together other topical medicine.
- Children under 12 years of age may not use this medicine.

USE CAREFULLY NIMEKSIL in the following situations

- NIMEKSIL do not apply to eye, mucosa, skin with infection or open wounds on the skin. In case of accidental contact, rinse immediately with plenty of water.
- Do not take by mouth. Wash hands after application.
- If irritation, redness or itching occurs at the application site due to the use of NIMEKSIL, discontinue use and consult your doctor or hospital.
- Children under 12 years of age may not use this medicine.
- Use with caution in patients with gastrointestinal bleeding, active or possible gastric ulcer, severe renal or hepatic insufficiency, severe blood clotting disorders or severe / uncontrollable heart disease.
- To reduce the sense of sensitivity to light, do not expose to direct sunlight.
- Do not apply NIMEKSIL on larger areas for a long time.
- Do not contact NIMEKSIL with your clothes during application. Otherwise you may dye your clothes. This is eliminated by washing clothes.
- Do not cover the application area with bandage or any other material after applying NIMEKSIL.
- Undesirable side effects can be reduced by using the least effective dose for the shortest possible time.

If these warnings are valid for you at any time in the past, please consult your doctor.

Usage of NIMEKSIL with food and drink.

NIMEKSIL has no interaction with food and drinks.

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Pregnancy

Consult your doctor or pharmacist before using this medication.

NIMEKSIL is not recommended for use during pregnancy. Especially NIMEKSIL should not be used in the 3rd period of pregnancy.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

It is not known whether nimesulide is excreted in breast milk. Therefore, it is not recommended to be used during breastfeeding.

Do not apply NIMEKSIL on breast area before breastfeeding.

Driving and using machines

NIMEKSIL should not affect your ability to drive or operate machinery.

Important information about some of the inactive ingredients of NIMEKSIL

NIMEKSIL contains propylene glycol that may cause skin irritation.

Usage with the other medicines

NIMEKSIL has no known interaction with other medicines.

You do not use NIMEKSIL together other topical medicine.

Please inform your doctor or pharmacist if you are using or have recently used any medicine with or without a prescription.

3. How to take NIMEKSIL?

Instructions for proper use and dose / application frequency:

Apply NIMEKSIL to the affected area 2 or 3 times a day. The recommended treatment period is 7-15 days.

Administration way and method:

NIMEKSIL uses for topical only. Apply NIMEKSIL gently to the affected area until fully absorbed. Do not apply bandage or closure during treatment. Do not rub NIMEKSIL strongly on the affected area.

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Different age groups:

Use in children:

Children under 12 years of age should be given only with the suggestion and control of a doctor.

Use in the elderly:

NIMEKSIL is not recommended for elderly patients.

Special use cases:

NIMEKSIL cream has no special used case.

If you notice that the effect of NIMEKSIL is too strong or not strong enough, talk to your doctor or pharmacist.

Kidney / Liver failure:

If you have kidney or liver problems, consult your doctor before using NIMEKSIL.

If you notice that the effect of NIMEKSIL is too strong or not strong enough, talk to your doctor or pharmacist.

If you use more NIMEKSIL than you need:

If you use NIMEKSIL more than necessary, talk to a doctor or pharmacist

If you forget to use NIMEKSIL:

Do not apply double doses to compensate for forgotten doses.

Possible effects after completion of NIMEKSIL treatment

No effect is likely to happen after completion of treatment. Do not stop NIMEKSIL treatment unless asked by your doctor.

4. What are possible side effects?

Side effects are classified as following categories:

Very common : minimum 1 in 10 patients are affected

Common : fewer than 1 in 10, but more than 1 in 100 patients are affected

Uncommon : fewer than 1 in 100, but more than 1 in 1000 patients are affected

Rare : fewer than 1 in 1000 patients are affected

Very rare : fewer than 1 in 10,000 patients are affected

Not known : frequency cannot be estimated from the available data

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If you notice any of the following, tell your doctor:

In the application area;

Uncommon

- Pruritus
- Rubescence

Not known

- Mild or moderate skin irritation
- Peeling
- Skin rash
- Itching

If you get any side effects not listed in this leaflet, please give information to your doctor or pharmacist.

Reporting side effects

Talk to your doctor, pharmacist or nurse if you have any side effects that are included or not in the leaflet. Also report any side effect you may encounter to the "Drug Side Effects Report" at www.titck.gov.tr or call 0 800 314 00 08 "Turkey Pharmacovigilance Center (TUFAM)" side effect notification line. By reporting side effects, you will contribute to learning more about the safety of the medicine you are using.

5. How to store NIMEKSIL?

Keep NIMEKSIL out of the reach and sight of children, in the its original package.

Keep this medicine at room temperature lower than 25°C.

Use as agreeable with expiration dates.

Do not use NIMEKSIL after the expiration date on the packaging.

If you notice any defects in the product and/or package, do not use NIMEKSIL.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanism.

Registration Holder: Terra İlaç ve Kimya San. Tic. A.Ş.
Ümraniye/İstanbul

Manufacturer: Myfarma İlaç San. ve Tic. A.Ş.
Tuzla / İstanbul

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