Patient Leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986
This medicine is dispensed without a doctor's prescription

N-Ke'ev

Active ingredient and its quantity in a dose unit:
Diclofenac Sodium 1%

Inactive ingredients in the preparation: see section 6 "Additional information", and in section 2 "Important information about some of the medicine's ingredients".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have other questions, refer to the doctor or the pharmacist.

You should use the preparation properly. Consult the pharmacist if you have further questions. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 7 days.

1. What is the medicine intended for?

Self-treatment for the following indications:
Local treatment of pain, inflammation and swelling due to:
- Pain, inflammation and swelling due to injury to: tendons, ligaments, muscles and joints, e.g. due to sprains, strains, bruises and/or back pain (such as: sports injuries).
- Localized forms of soft tissue rheumatism, such as tendinitis (e.g., tennis elbow), bursitis.

According to a doctor's order:
- Pain due to osteoarthritis of the peripheral joints, such as the knee or fingers.

Therapeutic class: N-Ke'ev contains the active ingredient diclofenac, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

2. Before using the medicine

Do not use the medicine if:
- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (see section 6).
- You are in the last trimester of your pregnancy (see also the section on pregnancy and breastfeeding).
- You have previously had an allergic reaction to diclofenac or to other medicines for treatment of pain, fever or inflammation, such as: aspirin (acetylsalicylic acid) or ibuprofen.
  Symptoms of an allergic reaction to these medicines may include: asthma, wheezing or shortness of breath; skin rash or urticaria; swelling of the face or tongue; runny nose.
- You are using other medicines that contain diclofenac, or are taking medicines of the NSAIDs family, such as oral aspirin or ibuprofen.
- You are under 12 years old.

Special warnings regarding the use of this medicine

- **Do not apply the gel to skin with:**
  1) Rash or eczema.
  2) Cuts or open wounds.
  Discontinue treatment if a skin rash develops following application of the preparation.
- Refrain from application to large skin areas and for a prolonged period, unless a doctor orders it.
- Extra care should be taken while sunbathing or when using tanning lamps, since your skin may be more sensitive to sunlight.
- If you are suffering or have previously suffered from a peptic ulcer or a duodenal ulcer, tell your doctor or the pharmacist before using the gel.
- If you suffer or have previously suffered from asthma, tell your doctor or the pharmacist before using the medicine.

Drug interactions
If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Do not use N-Ke'ev if you are already taking diclofenac tablets or other analgesic/nonsteroidal anti-inflammatory drugs tablets (NSAIDs) (such as aspirin or ibuprofen).

Pregnancy and Breastfeeding
If you are pregnant or breastfeeding, think you might be pregnant or are planning to become pregnant, consult your doctor or pharmacist before using this medicine.
Do not use N-Ke'ev during the last trimester of pregnancy since it may harm your fetus or cause problems during labor.
N-Ke'ev may be used only according to a doctor's order during the first six months of pregnancy, while maintaining the lowest dosage and the shortest treatment period possible. A possible side effect of this medicine is kidney damage in the fetus and low levels of amniotic fluid starting from the 20th week of pregnancy. It is recommended to avoid using medicines from the NSAIDs group starting from the 20th week of pregnancy and to consult a healthcare professional if necessary.
In breastfeeding women, N-Ke'ev should be used only according to a doctor's order since diclofenac passes in small doses to the breastmilk. However, N-Ke'ev should not be applied to a breastfeeding mother's breast or to other large skin areas for a prolonged period of time. Consult your doctor or pharmacist for more information if you are pregnant or breastfeeding.

Driving and operating machinery
When used according to the instructions, N-Ke'ev is not expected to affect your ability to drive or operate machinery.

Important information about some ingredients of the medicine
In addition to the active ingredient, N-Ke'ev contains the following ingredients:
- Propylene glycol which may cause mild local skin irritation in some people.
- Propyl parahydroxybenzoate and methyl parahydroxybenzoate which may cause an allergic reaction (sometimes delayed).

3. How should you use the medicine?

Check with the doctor or pharmacist if you are not certain about the dosage and how to use the preparation.
The generally accepted dosage is: rubbing a small amount of N-Ke'ev into the skin in the area with pain and/or swelling 3-4 times a day. The amount of the gel depends on the size of the injured area. An amount between a cherry and a walnut in size (2-4 grams) is usually sufficient. A slightly cold sensation may be felt while rubbing in the gel. Wash your hands after using N-Ke'ev unless they are the treated area.
This medicine is not intended for children under 12 years of age.
The duration of treatment depends on the injury and the clinical response.
Do not use N-Ke'ev for more than 14 days for soft tissue injuries or for rheumatic diseases of soft tissues, unless it is recommended by a doctor, and for more than 21 days for pain due to osteoarthritis.
If no improvement is felt in your condition within 7 days or if it is worsening, contact the doctor.
Avoid using other topical preparations on the area treated with N-Ke'ev.
Do not exceed the recommended dose.
Do not swallow! This medicine is intended for external use only.
Do not apply to infected skin or open wounds. Avoid having the preparation touch the eyes and mucous membranes. If this does happen, wash the eyes with water and inform the doctor.
N-Ke'ev may be applied under a bandage but not under an air-tight bandage.
If you accidentally apply a higher dosage
If you applied an overdose or if a child has accidentally swallowed this medicine, go to the doctor or the emergency room of a hospital immediately and take the package of the medicine with you.
If you forgot to apply the medicine
If you forgot to apply the medicine at the required time, apply the medicine as soon as you remember and then continue treatment with the gel as usual.
Do not apply a double dose as a compensation for the forgotten dose.

Medicines should not be taken in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them. If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side Effects

As with any medicine, using N-Ke'ev may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Some of the rare or very rare side effects may be severe.
Discontinue treatment and contact a doctor or pharmacist immediately if any of the following allergy signs occur:
- Skin rash accompanied by blisters, urticaria (may occur in 1-10 out of 10,000 users).
- Wheezing, shortness of breath or feeling of chest tightness (asthma) (may occur in less than one out of 10,000 users).
- Swelling of the face, lips, tongue, or throat (may occur in less than one out of 10,000 users).

Other side effects that may occur are usually mild, transient, and harmless (if you are concerned, contact a doctor or a pharmacist).
Common side effects (may occur in 1-10 out of 100 users):
Rash, itching, redness or a sharp pain in the skin.
Very rare side effects (may occur in less than one out of 10,000 users):
The skin may be more sensitive to sunlight. Possible signs are: a sunburn accompanied by itching, swelling and blisters.
If a side effect occurs, if any of the side effects worsen, or if you suffer from a side effect not mentioned in the leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/
In addition, you can also report to the following email: safety@trima.co.il

5. How to store the medicine?

Prevent poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the tube or on the package. The expiry date refers to the last day of that month.
After the first opening, the gel can be used for 12 months.
Store in a cool place below 25°C. Do not freeze.
Do not throw medicines in the trash when you finish using them, consult a pharmacist on how you should discard unneeded medicine.
These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Purified water, propylene glycol, diethylene glycol monoethyl ether, coco-caprylate/caprate, macrogol cetostearyl ether, carbomer 934P, essence lavender, methyl parahydroxybenzoate, propyl parahydroxybenzoate, strong ammonia solution.

What does the medicine look like and what are the contents of the package?
N-Ke'ev is an off-white to ivory-colored gel contained in an aluminum tube closed with a screw cap. Each tube contains 50 grams. The package contains one tube or two tubes. Not all pack sizes may be marketed.

Name and address of the manufacturer and license holder:
Trima Israel Pharmaceutical Products Maabarot Ltd. Maabarot 4023000, Israel.

Revised in February 2023 according to the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 140-07-31948-00

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Israel Pharmaceutical Products
Maabarot Ltd.

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