

**PATIENT PACKAGE INSERT IN
ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed without a doctor's prescription

N-Keev, Gel

1) MEDICINE NAME, DOSAGE FORM AND POTENCY:

Medicine name: N-Keev

Dosage form: Gel.

Composition of active ingredient and its concentration in a single dosing unit: Diclofenac sodium 1%

For the list of inactive ingredients and allergens in the preparation – see section 6, "Further information".

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

The medicine is intended for adults (both men and women) and adolescents above 12 years of age. Under this age, refer to a doctor. Use the medicine properly. Consult the pharmacist if you need further information.

Refer to a doctor if signs of the illness (symptoms) worsen or do not improve after 7 days.

What is the medicine intended for? The medicine is intended for topical treatment of rheumatic diseases and topical treatment of pain and non-infectious inflammation.

Therapeutic group: Non-steroidal anti-inflammatory drugs (NSAID's).

2) BEFORE USING THE MEDICINE:

Do not use the medicine:

- if you are sensitive (allergic) to the active ingredient, or any of the other ingredients contained in the medicine. The active ingredient appears in section 1 and the other ingredients are outlined in section 6.
- if you are pregnant or breastfeeding.
- if you had a previous allergy to diclofenac or to one of the ingredients of the medicine or to other medicines used to treat pain, fever or inflammation, such as: acetyl-salicylic acid or ibuprofen or other medicines from the NSAID's family. Symptoms of an allergic reaction include: asthma, shortness of breath, wheezing when breathing, skin rash, swelling of the face or the tongue, runny nose.
- on open wounds or on irritated skin. In addition, avoid contact with the eyes and mucous membranes.
- adjacent (immediately before and/or after) bypass surgery.
- do not use concomitantly with other oral medicines from the NSAID's family, or medicines containing diclofenac (also see later in this section).

Special warnings regarding use of the medicine:

- The medicine is intended for external use only.
- Do not use this medicine frequently or for a long period of time without consulting the doctor.

– If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

– It is not recommended to use this medicine on large areas of the skin without consulting a doctor.

– During treatment, avoid exposure of the treated area to natural sunlight or to a tanning ultra-violet (UV) lamp. The safety of concomitant use (on the same treatment area) of diclofenac sodium and sunscreen lotion (sunlight protection), cosmetic products and/or other medications for skin treatment, has not been tested.

– In order to avoid appearance of side effects, use the smallest amount of the medicine that achieves the desired effect, and for the shortest possible duration.

– Use of the medicine in case of an acute kidney disease is not recommended. Nevertheless, if you use the medicine, kidney function should be closely monitored.

Before treatment with the medicine, tell the doctor: If you suffer, or have suffered in the past, from impaired function of: the liver, the kidneys, the digestive system (e.g., ulcer), the heart, hypertension, asthma.

If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking medicines from the following groups:

- Acetylsalicylic acid, other salicylates, and other non-steroidal anti-inflammatory preparations (the NSAID's family).
- Oral steroids, anticoagulants, antibiotics, antiepileptic medicines, diuretics, antihypertensives of the ACE inhibitor family, lithium, methotrexate, cyclosporine.

Pregnancy and breastfeeding: Do not use the medicine when you are pregnant or breastfeeding.

Driving and operating machines: There is no effect on ability to drive and operate machines.

3) HOW SHOULD YOU USE THE MEDICINE?

Always use according to the instructions. Check with the doctor or pharmacist if you are uncertain how to use it.

The usual dosage is generally: Massage a small amount of the medicine into the skin, at the site of pain and/or swelling, 3-4 times a day. The quantity of the medicine depends on the size of the affected area. Usually, an amount the size of a cherry to a walnut (2-4 gr) is sufficient. You may feel a slight cool sensation while massaging the medicine.

Wash your hands after using the medicine, unless they are the treated area.

This medicine is not usually intended for children under 12 years of age.

Treatment duration depends on the injury and the clinical response. Do not use this medicine for more than 14 days for soft tissue injuries or for rheumatic soft tissue diseases unless recommended by a doctor.

If your condition does not improve within 7 days or it worsens, refer to a doctor.

Avoid use of additional topical medicines in the area treated with this medicine .

Do not exceed the recommended dose. Do not swallow! This medicine is intended for external use only.

Do not apply to affected skin or open wounds, and take care that the medicine does not come into contact with the eyes and mucous membranes. If this occurs, rinse the eyes with water and inform the doctor.

The medicine can be applied under a dressing but not under an airtight dressing.

Tests and follow-up: When applying the medicine according to the doctor's instructions, at high dosage or for a long period of time, it is recommended to undergo lab tests (blood, urine, liver and kidney function) in order to ensure that the test results are in the normal range. There may be an elevation in liver enzymes which requires cessation of the treatment after consulting the doctor.

If you took an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to apply this medicine at the designated time, do not apply a double dose. Apply the dose as soon as possible, and apply the next dose at the regular time.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4) SIDE EFFECTS:

As with any medicine, use of this medicine may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Discontinue use and immediately refer to a doctor or proceed to a hospital emergency room, if the following effects develop:

- Severe skin rash accompanied by warts and urticaria (edematous rash).
- Shortness of breath or difficulty breathing, asthma.
- Swelling of the face, lips, tongue or throat.
- Exfoliative dermatitis, widespread rash with skin blistering and peeling, especially around the mouth, nose, eyes and genitals (Steven's Johnson syndrome), and a more acute form of the rash that causes widespread peeling of the skin (TEN).

Additional side effects: Occurring frequently at a prevalence of up to 1:100: dermatitis (skin inflammation, including contact dermatitis), rash, skin redness, eczema, itching.

Side effects occurring very rarely: hypersensitivity to sunlight. Possible symptoms are: sunburn accompanied by itching, swelling and blistering.

In case liver dysfunction is suspected, which can be manifested by nausea, increase in transaminases (liver enzymes), tiredness, sleepiness, diarrhea, itching, jaundice (yellowing of the skin and eyes), tenderness of the upper right side of the abdomen and flu-like symptoms; discontinue treatment and refer to a doctor immediately.

When used on large areas of the skin and for a long period of time, absorption into the circulatory system is possible. In such a case, side effects characteristic of oral administration of the medicine may appear: nausea and digestive system disorders, skin rash, impaired liver function, dizziness, headaches (rare); discontinue treatment and refer to a doctor.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health through the online form for reporting side effect found on the Ministry of Health homepage: www.health.gov.il

or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5) HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (Exp. Date) that appears on the tube or package. The expiry date refers to the last day of that month.

Storage conditions: Store in a cool place, at a temperature below 25°C. Do not freeze.

After first opening the tube, the medicine can be used within one year (12 months)

6) FURTHER INFORMATION:

In addition to the active ingredient, the medicine also contains the following excipients:

Purified Water, Propylene Glycol, Diethylene Glycol Monoethyl Ether, Coco-Caprylate/Caprate, Macrogol Cetostearyl Ether, Carbomer, Essence Lavender, Methylhydroxybenzoate, Propylhydroxybenzoate, Strong Ammonia Solution.

What does the medicine look like and what are the contents of the package: The medicine is a cream (off-white) to yellowish-white (ivory) colored gel. The gel is packaged in metal tubes with a plastic screw-on cap. Each tube is packaged in a carton box.

License holder: Tree of Life Pharma, VAT # 513071621. P.O.B 799, Lod 7110604.

Manufacturer: Trima Israeli Pharmaceutical Products Maabarot Ltd., Kibbutz Maabarot in collaboration with Ben Shimon Floris Ltd., Tradyon.

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