Patient package insert according to
Pharmacists' Regulations (Preparations) - 1986
This medicine can be sold without a physician's prescription

DICLOVIT, Gel, 1% W/W

Composition:
Each tube contains: Diclofenac Sodium 1% W/W

Inactive ingredients and allergens in the medicine- see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".
Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or the pharmacist.
Take this medicine according to the instructions in section 3 "How to use this medicine?" in this leaflet.
Consult the pharmacist if you need additional information. Refer to a doctor if the symptoms of your illness get worse or if they 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 group: Diclovit contains the active ingredient diclofenac, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

2. Before using this medicine

Do not use this medicine if:

• You are hypersensitive (allergic) to the active ingredient (Diclofenac Sodium) or to any of the other ingredients this medicine contains
(see section 6 "Additional information").
• You are in the last trimester of your pregnancy (see in section 2 "Pregnancy and breastfeeding").
• You 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 while breathing 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 taking medicines of the NSAIDs family, such as oral Aspirin or Ibuprofen.
• You are under 12 years of age.

Special warnings regarding the use of the medicine
• This medicine contains Alcohol. Do not light a cigarrete or expose yourself to fire before the medicine has completely dried.
• Do not apply the gel to a skin with:
(1) Rash or eczema.
(2) Cuts or open wounds.
Discontinue treatment if a skin rash develops following application of the medicine.
• Refrain from application to large skin areas and for a prolonged period, unless a doctor orders it.
• Extra caution must 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 pharmacist before using the medicine.
• If you suffer or have previously suffered from asthma, tell your doctor or the pharmacist before using the medicine.
Children and adolescents:
This medicine is not intended for children under 12 years of age.
Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Do not use **Diclovit** if you are already taking Diclofenac tablets or other analgesic/ non-steroidal anti-inflammatory 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 **Diclovit** during the last trimester of pregnancy, since it may harm your fetus or cause problems during labor.

• **Diclovit** 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.
• This medicine has a possible side effect of kidney impairment in the fetus and low amniotic fluid levels starting from the 20th week of pregnancy. It is recommended to avoid using medicines from the NSAIDs family starting from the 20th week of pregnancy and to consult a healthcare professional, if necessary.
• **Diclovit** should be used only according to a doctor's order during breastfeeding since Diclofenac passes in small doses to breastmilk. However, **Diclovit** should not be applied to a breastfeeding mother's breast or to other large skin areas for a prolonged period.
• Consult your doctor or pharmacist for more information if you are pregnant or breastfeeding.
Driving and using machines:
When used according to the instructions, **Diclovit** is not expected to affect your ability to drive or operate machines.
Important information about some of the ingredients of this medicine
• The medicine contains Propylene Glycol, which may cause skin irritation.
• The medicine contains Butylated Hydroxytoluene (E 321), which may cause local skin reactions (e.g., Contact Dermatitis), or irritation to the eyes and mucous membranes.

3. How to use this medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.
The usual dosage is generally:
Rubbing a small amount of **Diclovit** into the skin in the pain and/ or swelling area 3 - 4 times a day.
The amount of 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 the gel. Wash your hands after using **Diclovit**, unless your hands are the treated area.

The duration of treatment depends on the injury and the clinical response.
Do not use **Diclovit** 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 in your condition is felt within 7 days or if it is worsening, contact the doctor.
Avoid using other topical medicines on the area treated with **Diclovit**.
Do not exceed the recommended dose.

Method of administration:
• Do not swallow! This medicine is intended for external use only.
• Do not apply to infected skin or open wounds. Avoid contact of the medicine with the eyes and mucous membranes. If this does happen, wash the eyes with water and inform the doctor.
• **Diclovit** may be applied under a bandage but not under air-tight bandage.
If you have accidentally applied a higher dosage
If you applied an overdose or a child has accidentally swallowed the medicine, proceed immediately to a doctor or hospital emergency room and bring the package of the medicine with you.
If you forgot to apply the medicine
If you forgot to apply this medicine at the designated time, apply the medicine as soon as you remember and then continue treatment with the medicine as usual. Do not apply a double dose to make up for a forgotten dose.
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions on the use of this medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, the use of **Diclovit** may cause side effects in some users. Do not be alarmed when reading the list of side effects.
You may not suffer from any of them.
Some of the rare or very rare side effects may be severe. Discontinue treatment and consult a doctor or pharmacist immediately if any of the following allergy signs occur:
• Skin rash accompanied by blisters, urticaria (effects that appear in 1-10 out of 10,000 users).
• Wheezing while breathing, shortness of breath or feeling of chest tightness (asthma) (effects that appear in less than one out of 10,000 users).
• Swelling of the face, lips, tongue or throat (effects that appear 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 (effects that appear in 1-10 out of 100 users):
Rash, itching, redness or a sharp pain in the skin.
Very rare side effects (effects that appear 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 appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.
Report of side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications and drugs" on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects, or by following the link: https://sideeffects.health.gov.il

5. How to store the medicine?

• Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/ or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
• Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
• **Storage conditions:** Store below 25°C.
• The medicine can be used for up to 6 months after opening the tube for the first time, and no later than the expiry date, that appears on the package.
• Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Purified Water, Macrogol Cetostearyl Ether (Cetomacrogol 1000), Glyceryl Cocoate (PEG-7), Propylene Glycol, Oleyl Alcohol, Triethanolamine, Polyacrylic Acid (Carbomer 934P), Methylparaben, Imidazolidinyl Urea (Imidurea), Oleum Citri (Lemon Oil), Menthol Eucalyptus Oil, Propylparaben, Butylated Hydroxytoluene (E 321).
What the medicine looks like and what the package contains:
Diclovit is a white to yellowish gel, packed in an aluminum tube.
Approved package sizes: 50 grams, 100 grams.
Not all package sizes may be marketed.

Manufacturer and registration holder:
Vitamed Pharmaceutical Industries Ltd.,
6 Hatahana St., P.O.B. 114, Binyamina 3055002, Israel.
Revised in June 2023 according to MOH guidelines.
Drug registration number at the national drug registry of the Ministry of Health: 111-42-29399-00