PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Voltaren emulgel 1%

Active ingredient and its quantity in a dose unit:

Diclofenac Sodium (as Diclofenac Diethylamine) 1%

Additional ingredients are listed in section 6.

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

You should use the medicine 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

Voltaren emulgel 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 this medicine if:

- You are sensitive (allergic) to the active ingredient or any of the additional components the medicine contains (see section 6).
- You are in the last trimester of your pregnancy (see also the pregnancy and breastfeeding section).
- 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 the medicine

- The preparation contains alcohol. Do not light a cigarette or expose yourself to fire before the preparation 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 preparation.
- Refrain from application to large skin areas and for a prolonged period of time, 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 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-drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist.

Do not use Voltaren emulgel 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 Voltaren emulgel during the last trimester of pregnancy, since it may harm your fetus or cause problems during labor.

Voltaren emulgel 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 preparation 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 preparations from the NSAIDs family starting from the 20th week of pregnancy and to consult a healthcare professional if necessary.

In breastfeeding women, Voltaren emulgel should be used only according to a doctor's order since diclofenac passes in small doses to breastmilk. However, Voltaren emulgel 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, Voltaren emulgel is not expected to affect your ability to drive or operate machinery.

Important information about some ingredients of the medicine

The gel contains propylene glycol and benzyl benzoate which may cause mild local skin irritation in some people.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The generally accepted dosage is:

Rubbing a small amount of Voltaren emulgel into the skin in the pain and/or swelling area 3 - 4 times a day.

The amount of emulgel 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 emulgel. Wash your hands after using Voltaren emulgel, 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 Voltaren emulgel 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 preparations on the area treated with Voltaren emulgel.

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. Voltaren emulgel may be applied under a bandage but not under air-tight bandage.

If you accidentally apply a higher dosage

If you applied an overdose or a child 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 <u>every time</u> 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 Voltaren emulgel 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 a 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 one of the side effects worsens, or if you suffer from a side effect not mentioned in this 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/

5. How to store the medicine?

Avoid 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 an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

After opening, the preparation may be used until the expiry date appearing on the package.

Storage conditions: store at a temperature lower than 30°C.

Do not throw medicines to the trash when you finish using them, consult a pharmacist how you should discard an unneeded medicine. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains:

Purified water, Isopropyl alcohol, Propylene glycol (1,2 Propylene glycol, dist.), Liquid paraffin, Mineral Oil (Liquid Paraffin, heavy), Cocoyl Caprylocaprate (Cetiol LC), Macrogol cetostearyl ether (Cetomacrogol 1000), Carbomers (Carbopol 947 P), Diethylamine, Perfume Cream 45.

What does the medicine look like and what are the contents of the package

Volatren emulgel is a gel, packed in an aluminum tube.

The tube is available in package sizes of 10 grams, 20 grams, 30 grams, 50 grams, 100 grams, 120 grams and 150 grams. Not all package sizes may be marketed.

License holder and the address: GSK Consumer Healthcare Israel Ltd., P.O. Box 3256, Petah Tikva

Name and address of the manufacturer:

GSK Consumer Healthcare S.A., Nyon, Switzerland.

This leaflet was reviewed and approved by the Ministry of Health in February 2019 and has been updated in accordance with the Ministry of Health instructions in July 2021.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 037-66-25000