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

This preparation is dispensed without a doctor's prescription

Voltaren Emulgel Forte 2%

Active ingredient and its quantity in a dose unit:

Diclofenac diethylamine 2.32%

(Corresponds to Diclofenac sodium 2.0%)

For a list of inactive ingredients and allergens in the preparation – see 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. Use the preparation according to the instructions in section 3 – "How should you use the medicine?" in this leaflet. You should use the medicine properly. Consult the pharmacist if you need more information. 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?

The medicine is intended for use without a doctor's order for the following indications:
Local treatment of pain, inflammation and swelling in adults and adolescents over 12 years of age, in the following cases:
Trauma of the tendons, ligaments, muscles and joints due to sprain, strain, bruise and/or back pain (e.g., sports injuries).
Local soft tissue rheumatic diseases, such as tendonitis (e.g., tennis elbow) and bursitis.
Do not use for more than 14 days.

According to a doctor's order, the medicine is intended for treatment of pain due to osteoarthritis of the joints, such as the knee or fingers.

Therapeutic class:
Voltaren Emulgel Forte 2% contains the active ingredient diclofenac, which belongs to the class of non-steroidal anti-inflammatory drugs (NSAIDs). It has a special formulation which enables it to be rubbed into the skin.

2. Before using the medicine

Do not use the preparation if:

- You are sensitive (allergic) to the active ingredient (diclofenac diethylamine) or to other medicines for treatment of pain, fever or inflammation, such as ibuprofen or aspirin (a medicine used to treat blood coagulation), or to any of the additional components the medicine contains. Symptoms of an allergic reaction may manifest as shortness of breath or wheezing while breathing (asthma), skin rash with blisters or urticaria, swelling of the face or tongue, runny nose.
- You have recently been suffering from severe joint pains that are not related to an injury or in times of excessive use.
- You feel unwell, you have a fever or another symptom alongside the pain.
- You are in the last trimester of pregnancy.

Do not use this medicine if you have one or more of the symptoms listed above.

Do not use the preparation in children under the age of 12.

Special warnings regarding the use of the medicine

- Do not apply the emulgel on a rash or eczema, cuts or open wounds. Stop the treatment if a skin rash appears following application of the medicine.
- Avoid application on large skin areas and for a prolonged period of time, unless the doctor recommends it.
- Care should be taken while sunbathing or when using tanning lamps, as your skin may be more sensitive to sunlight.

- Voltaren Emulgel Forte 2% is intended for topical use only. Do not use it orally and do not swallow it. Wash your hands after use, unless your hands are the treated area. Avoid contact of Voltaren Emulgel Forte 2% with the eyes.

  If this happens, wash your eyes thoroughly with clean water. If the discomfort continues, speak to the doctor or pharmacist.
- Due to increased risk of side effects, care should be taken when taking other medicines that contain analgesics (NSAIDs), such as aspirin or ibuprofen.
- A splint or wound dressing may be used, but do not apply the emulgel under an air-tight dressing (plastic).
- If you are suffering or have previously suffered from a gastric or a duodenal ulcer, tell your doctor or pharmacist before using the emulgel.
- If you are suffering or have previously suffered from asthma, tell your doctor or pharmacist before using the emulgel.
- Do not go near an open fire or smoke in its vicinity – there is a risk for severe burns. Fabric (clothes, bed linen, dressings etc.) that was in contact with the medicine will burn more easily and is a serious fire hazard. Washing clothes and bed linen can decrease the accumulation of the material, but not remove it completely.

If you have any questions, refer to the doctor or pharmacist before using the medicine.

Do not use the preparation in children under the age of 12.

Children and adolescents
The medicine is intended for adults and adolescents over 12 years old. Below this age – contact the doctor.

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

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, thinking you might be pregnant or are planning to become pregnant, ask the doctor before using the medicine.

Pregnancy:
Do not use Voltaren Emulgel Forte 2% if you are in the last trimester of pregnancy, since the preparation may harm the fetus or cause problems during delivery. Do not use the preparation during the first six months of pregnancy unless the doctor orders it; the lowest dosage should be used for the shortest period of time 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.

Breastfeeding:
Do not use Voltaren Emulgel Forte 2% unless a doctor orders it, since diclofenac passes into breastmilk in small amounts. Breastfeeding women should not apply Voltaren Emulgel Forte 2% on their breasts, nor on large areas or for a prolonged period of time.

If you are pregnant or breastfeeding, consult the doctor or pharmacist for more information.

Important information about some ingredients of the medicine
- **Propylene glycol** – may cause mild local irritation in some people.
- **Butylhydroxytoluene** – may cause local skin reactions (e.g., contact dermatitis) or eye and mucosal irritation.

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 for children, adolescents over 12 years of age and adults is:
Apply the preparation twice daily (morning and evening) to the painful area, which will relieve the pain for up to 12 hours.

Do not exceed the recommended dose.
How should you use the medicine:
Do not use if tamper evidence seal is broken.

1. Opening
   a) *For a flip-top cap:*
      Use your finger, thumb, side of the hand or even a table's edge against the bottom part of the cap to easily open the pull-out cap.
   b) *For a screw-on cap:*
      Before the first use, remove the cap, insert it backwards into the tube and rotate it to remove the film covering the tube's opening.
2. Rub a small amount of Voltaren Emulgel Forte 2% into the skin in the painful/swollen area. The amount of emulgel depends on the size of the injured area. You may feel a slightly cold sensation while rubbing the emulgel.
3. Following use, wipe any leftover gel from the pull-out cap as necessary using a cotton cloth or paper towel, until it appears clean and dry. Close the pull-out cap until you hear a "click". Hold the tube upright when opening or closing the pull-out cap to prevent the gel from leaking.
4. Wash your hands after using Voltaren Emulgel Forte 2%, unless your hands are the treated area.

Do not swallow. The preparation is intended for external use only.

Voltaren Emulgel Forte 2% may be used for up to 14 days; further use should be according to a doctor's recommendation only.

If no improvement in your condition is felt within 7 days or if it is worsening, contact the doctor.

If you accidentally took a higher dosage
If you used more gel than was necessary, wipe the excess gel with a tissue paper.
If you took an overdose or if 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 take this medicine
If you forgot to apply this medicine at the required time, apply it when you remember and apply the next dose at the regular time. Do not apply it more than twice daily. Do not apply a double dose.

Do not take medicines 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 the use of the medicine, consult the doctor or the pharmacist.

4. <u>Side effects</u>

As with any medicine, using Voltaren Emulgel Forte 2% 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 and very rare side effects may be serious.

Discontinue treatment with the medicine and contact a doctor immediately if you experience signs of allergy:

- Skin rash with blisters, hives (red, itchy, raised lesions) (may occur at an incidence of up to 1:1,000).
- Wheezing while breathing, shortness of breath or a sensation of tightness in the chest (asthma) (may occur at an incidence of up to 1:10,000).
- Swelling of the face, lips, tongue or throat. (may occur at an incidence of up to 1:10,000).

Additional side effects which may occur are usually mild, transient and harmless.

Very common side effects (side effects that occur in more than one out of ten users):

- Skin rash, skin reddening, itching.

Very rare side effects (side effects that occur in less than 1 out of 10,000 patients):

- Hypersensitivity of the skin to the sun. Signs may be a sunburn accompanied by itching, swelling and blisters.

Side effects with unknown frequency
(effects whose frequency has not yet been determined):

- Irritation in the treated area, exfoliation and skin discoloration.

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 and sight 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.
- Storage: Store at a temperature lower than 25°C.
- After opening the product, it may be used up to the expiry date (exp. date) appearing on the package.

The expiry date refers to the last day of that month.

6. Additional information

In addition to the active ingredient the medicine also contains:
Purified Water, Isopropyl Alcohol, Propylene Glycol, Cocoyl Caprylocaprate, Liquid Paraffin, Macrogol Cetostearyl Ether, Carbomer Diethylamine, Oleyl Alcohol, Perfume Eucalyptus Sting, Butylhydroxytoluene.

What does the medicine look like and what are the contents of the package:
Voltaren Emulgel Forte 2% is a white, non-oily gel.
The preparation comes in packages of 50, 100 and 150 grams. Not all package sizes may be marketed.

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

Name and address of the manufacturer:
GSK Consumer Healthcare SARL, Nyon, Switzerland.

Registration number of the medicine in the national drug registry of the Ministry of Health:
1526333919

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health on September 2014, and has been updated in accordance with the Ministry of Health instructions on July 2021.

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