

Package Leaflet: Information for the user

Voltaren Emulgel 23.2 mg/g (2.32%) gel diclofenac diethylamine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use Voltaren Emulgel exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

1. What Voltaren Emulgel is and what it is used for
2. What you need to know before you use Voltaren Emulgel
3. How to use Voltaren Emulgel
4. Possible side effects
5. How to store Voltaren Emulgel
6. Contents of the pack and other information

1. What Voltaren Emulgel is and what it is used for

The active substance of Voltaren Emulgel, diclofenac, belongs to the group of medications called non-steroidal anti-inflammatory analgesics. It is a highly skin-permeable gel for rubbing into the skin. The active substance reaches the deeper inflamed areas of the tissues.

Voltaren Emulgel gel is used in adults and children above 14 years for topical treatment of pain, inflammation and oedema in case of soft tissue damage (e.g. muscle and joint injuries (dislocations, strains, bruises, backache, sports injuries), tendonitis, forearm or knee oedema).

2. What you need to know before you use Voltaren Emulgel

Do not use Voltaren Emulgel

- If you are allergic to diclofenac or any other analgesic, fever-reducing and anti-inflammatory agent like ibuprofen or acetylsalicylic acid (also used as anticoagulant), or any other ingredient of this medicine (listed in section 6). You should check with your doctor or pharmacist if you are not sure.
- Symptoms of the allergic reaction induced by this medicine are the following: shortness of breath or breathlessness (asthma), pustular skin rash, facial or lingual oedema, allergic rhinitis.
- If you are pregnant (last trimester of pregnancy).
- If you are younger than 14 years.

Do not use Voltaren Emulgel if any of aforementioned applies to you.

Warnings and precautions

- Do not apply the medication if you have on your skin open wounds or rash or eczema. Discontinue the treatment if you develop skin rash after administration of the medication.
- Avoid long-term administration on large skin areas, unless under medical supervision.
- Voltaren Emulgel is meant for external use only. Do not administer orally. Do not swallow the medication. Avoid contact with eyes. Should it still happen, rinse your eyes with flowing water and contact your doctor or pharmacist.

- In case of injuries (dislocations) use regular, not airtight (plastic) bandages.

Keep the skin area treated protected from excessive sunlight.

If you have any further questions, ask your doctor or your pharmacist.

Children and adolescents (under 14 years of age)

There are limited data available about the efficacy and safety in children under 14 years of age (see section: “Do not use Voltaren Emulgel”)

Adolescents above 14 years of age: patient should consult the doctor if the treatment is to last for more than 7 days or if the symptoms worsen.

Other medicines and Voltaren Emulgel

Please inform your doctor, if you are taking or have recently taken any other medicines, including medicines available without prescription.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Do not use Voltaren Emulgel during the last trimester of pregnancy since it may harm your unborn baby and cause problems in labour. Voltaren Emulgel can be used during the first 6 months of pregnancy under medical supervision only, keeping the dosage as low and treatment duration as short as possible. Voltaren Emulgel can be used during breast-feeding with a doctor’s permission only, since diclofenac is excreted into breast milk in very small quantities. Nonetheless, Voltaren Emulgel should not be applied to breasts or large skin areas or used for a prolonged time.

If you are pregnant or breast-feeding, consult your doctor or pharmacist before using the medication.

Voltaren Emulgel contains propylene glycol and butylated hydroxytoluene

This medicine contains 50 mg of propylene glycol per gram of gel, which may cause skin irritation.

Butylated hydroxytoluene may cause local skin reactions (eg contact dermatitis) or irritation to the eyes and mucous membranes.

3. How to use Voltaren Emulgel

For skin use only.

Do not use in children under the age of 14 years.

Always use the medication exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 14 years

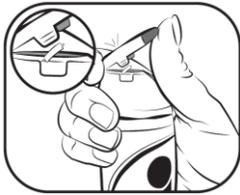
Apply Voltaren Emulgel twice daily (advisably in the morning and evening) on the sore area.

How to use Voltaren Emulgel

Aluminum laminated tube with screw cap:

- 1) To remove the seal before first-time use, unscrew and remove the cap. Place the cap reversed on the tube, twist and remove the seal from the tube.
- 2) Gently squeeze a small amount of the gel from the tube and rub it slowly on the sore or swollen skin area. The amount of medication applied depends on the size of the painful or swollen area; amount proportional to the size of a cherry up to the size of a walnut would usually be sufficient. You may notice a slight cooling effect when you rub the gel in.

Aluminum laminated tube with flip-off cap:



OR



1. Click open the cap.

To easily open the flip-off cap, press the bottom of the cap with your finger, thumb, or hand, or even against the edge of the table. When the lid is opened for the first time, the fastenings on each side of the flip-off cap break. Before using for the first time, make sure that the fastenings that allow the detection of opening are not broken.

2. Squeeze out the gel and rub it into the skin.

Gently squeeze a small amount of gel out of the tube and slowly rub it into the skin of the sore or swollen area. The amount of drug to be administered depends on the size of the area of pain or swelling; a sufficient amount is usually an amount of gel corresponding to the size of a cherry up to walnut. You may feel a slight cooling effect when rubbing the gel into your skin. To avoid accidental contact with mouth and eyes, wash hands thoroughly after administration, unless the area to be treated is hands (see section 2).



OR



3. Press on the cap to close it.

After use, remove the remaining amount of gel from the flip-off cap with a cotton towel or absorbent paper, if necessary, until it is visually clean and dry. To close the flip-off cap, press the top of the cap with your fingers, the side of your hand, or even against the edge of a table or work surface until you hear a click. When opening or closing the flip-off cap, keep the tube upright to prevent possible gel leakage.

After applying the gel:

- hands should be wiped clean with an absorbent paper towel and then washed if these are not areas to be treated. Absorbent paper towels should be disposed of with household waste after use.
- you must wait until Voltaren Emulgel 2.32% gel has dried on your skin before taking a shower or bath.

Voltaren Emulgel is for external use only.

For how long should you use Voltaren Emulgel

Do not use Voltaren Emulgel for longer than:

Adults and children over 14 years:

- 2 weeks in case of muscular and joint pain (e.g. dislocation, strain and bruises) or tendonitis (tendon inflammation),

Longer use of the medicine requires doctor's permission.

If the pain and swelling do not improve within 7 days or worsen, tell your doctor.

If you use more Voltaren Emulgel than you should

- If you have used more medication than you should, wipe the excess gel off the skin with an absorbent paper towel .
- If your child had accidentally swallowed the medication, contact your doctor immediately.

If you forget to use Voltaren Emulgel

If you have forgotten to apply Voltaren Emulgel at the correct time, do it as soon as you remember and then carry on as normal. Do not apply a double quantity to make up for the forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, Voltaren Emulgel can cause side effects, although not everybody gets them.

Some rare and very rare side effects may be serious.

If you develop any of the following allergy symptoms, STOP using Voltaren Emulgel and inform your doctor or pharmacist immediately:

- Pustular skin rash, urticaria (may affect 1 to 10 people in 10,000).
- Shortness of breath, breathlessness or tightness in chest (asthma) (may affect less than 1 person in 10,000).
- Facial, labial, lingual or pharyngeal oedema (may affect less than 1 person in 10,000).

Other adverse effects that may occur are usually modest, harmless and transient. If you are concerned, contact your doctor or pharmacist as soon as possible.

Common side effects (may affect 1 to 10 people in 100):

- Skin rash, itching (pruritus), redness or tingling.

Very rare side effects (may affect less than 1 person in 10,000):

- photosensitivity (skin may become sensitive to sunlight) Possible signs are sunburn with itching, oedema and blisters.

Unknown (frequency cannot be estimated from the available data)

- Burning sensation at the application site, dry skin.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Voltaren Emulgel

Keep out of the sight and reach of children.

Do not use Voltaren Emulgel after the expiry date which is stated on the package after “Kõlblik kuni:”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Voltaren Emulgel contains:

- The active substance is diclofenac diethylamine. 1 g of Voltaren Emulgel contains 23.2 mg of diclofenac diethylamine.
- The excipients are: butyl hydroxy toluene (E321), carbomer, cocoyl caprylocaprato, diethylamine, isopropyl alcohol, liquid paraffin, macrogol cetostearyl ether, oleyl alcohol, propylene glycol, eucalyptus fragrance, purified water (for additional information, see section 2).

What Voltaren Emulgel looks like and contents of the pack

Voltaren Emulgel white to off-white, cooling, non-greasy, non-staining cream-like gel.

The tube contains: 30 g, 50 g, 60, 100 g, 120, 150 or 180 g of gel.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

GlaxoSmithKline Dungarvan Limited
Knockbrack
Dungarvan
Co Waterford
Ireland

Manufacturers:

GlaxoSmithKline Consumer Healthcare GmbH & Co. KG
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