

Package leaflet: Information for the patient

Voltaren Emulgel 11,6 mg/g (1,16%) gel diclofenac diethylamine

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse 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.
- 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
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1. What Voltaren Emulgel is and what it is used for

The active substance diclofenac belongs to the group of medicines called non-steroidal anti-inflammatory painkillers. Voltaren Emulgel should be applied on the skin.

Voltaren Emulgel is used in adults and in adolescents over 14 years of age for local relief of pain, inflammation and swelling in case of soft tissue damage or rheumatic conditions (e.g. muscle and joint injuries (dislocation, sprain, bruising, back pain, sporting injuries), tendonitis, forearm or knee swelling).

If you have any questions on the effects of Voltaren Emulgel, ask your doctor or pharmacist.

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

Do not use Voltaren Emulgel:

- If you are allergic to diclofenac or other medicines used to treat pain or inflammation, such as ibuprofen or acetylsalicylic acid (also used to prevent blood clotting), or any of the other ingredients of this medicine (listed in section 6). Check with your doctor or pharmacist if you are not sure.

The symptoms of allergic reaction caused by this medicine include: rapid breathing or shortness of breath (asthma); blistering skin rash; swelling of face or tongue; allergic rhinitis.

- If you are pregnant (in the final trimester of pregnancy).
- If you are younger than 14 years.

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

Warnings and precautions

- Do not use Voltaren Emulgel if your skin has open wounds, rash or eczema. Discontinue treatment if you develop a rash after applying the medicine.

- Avoid use on large areas of skin and over a prolonged period of time, except if treatment is supervised by a doctor.
- Voltaren Emulgel is for external use only. Do not administer the medicine through oral route. Do not swallow the medicine. Wash your hands after applying the medicine. Prevent the medicine from getting into your eyes. If this happens, rinse your eyes with running water, and inform your doctor or pharmacist.
- You can use regular bandages in case of injuries (sprains), but not airtight (plastic) bandages.

Protect the treated skin area from excessive sunlight.

If you have any questions, consult your doctor or pharmacist before using Voltaren Emulgel.

Children and adolescents (under 14 years)

There are insufficient data on the efficacy and safety in children under 14 years (see also section “Do not use Voltaren Emulgel”).

Adolescents from 14 years of age: the patient should talk to a doctor if they need to use the medicine for longer than 7 days or if symptoms worsen.

Other medicines and Voltaren Emulgel

Tell your doctor if you are using or have recently used any other medicines, including over-the-counter medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Voltaren Emulgel should not be used during the last three months of pregnancy because it may harm your unborn child or cause complications at delivery. Voltaren Emulgel may be during the first 6 months of pregnancy only under medical supervision, keeping the dose as low as possible and treatment duration as short as possible. Voltaren Emulgel may be used only with the doctor’s consent during breast-feeding, as diclofenac passes into breast milk in small quantities. However, even in this case Voltaren Emulgel may not be applied on the breasts or on large skin areas, and should not be used for extended period of time.

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

Voltaren Emulgel contains propylene glycol and benzyl benzoate

This medicine contains 50 mg of propylene glycol per gram of gel, which may cause skin irritation. This medicine contains benzyl benzoate fragrances. Benzyl benzoate may cause allergic reactions.

3. How to use Voltaren Emulgel

For skin use only.

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children 14 years and older

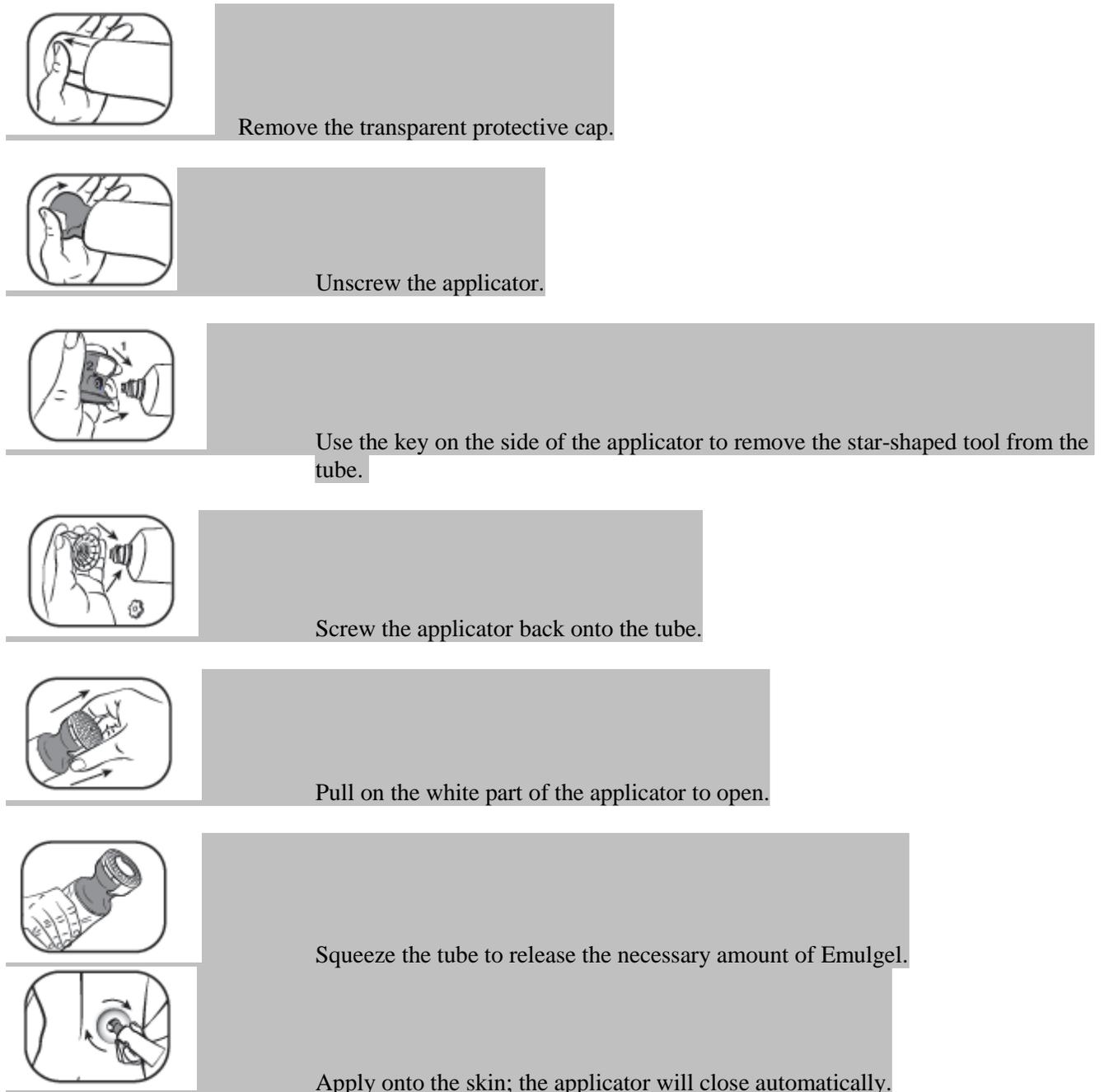
Apply Voltaren Emulgel to the painful area 3 to 4 times a day.

How to use Voltaren Emulgel

- To remove the tip cover before the first use, unscrew and remove the cap. Reverse the cap, place it on the tip, turn and remove the tube tip cover. Pack with applicator: to remove the cover before the first use, remove the transparent protective cap and unscrew the applicator. Use the star-shaped tool on the side of the applicator to remove the anti-forgery device from the tube. Reattach the applicator to the tube before application.

- Squeeze a small amount of gel from the tube and slowly rub it on the skin of the painful or swollen area. Pack with applicator: pull on the white part of the applicator to open. Gently squeeze some gel from the tube to the surface of the applicator. Use the applicator on the tube instead of your finger and rub the gel into the skin of the painful or swollen area. Applying gentle pressure while applying the gel will automatically close the applicator. The quantity of medicine depends on the size of the painful or swollen area; usually, an amount in the size of a cherry or walnut is sufficient (this amount can cover 400-800 cm² of skin). You may experience slight cooling effect while rubbing the gel into the skin.
- Wash your hands after applying Voltaren Emulgel, except when hands are the treated area. Pack with applicator: after use, clean the applicator with a cotton cloth or absorbable paper until the applicator looks dry and clean. Do not use any solutions or cleansing agents to clean the applicator. Do not use the applicator tube. Discard the tube with the applicator after use, pursuant to local regulations for the disposal of medicines.

Figure 1:





Clean the applicator with a cotton cloth or absorbable paper until the applicator looks dry and clean.

After applying the gel:

- Wipe your hands with an absorbent paper towel and then wash them if these are not areas to be treated. Absorbent paper towels should be disposed of in household waste after use.
- Wait in the shower or bath until Voltaren Emulgel 1.16% gel has dried on the skin.

Voltaren Emulgel is for external use only.

How long to use Voltaren Emulgel

Do not use Voltaren Emulgel for longer than:

Adults and children 14 years and older:

- 2 weeks in case of muscle and joint injuries (e.g. joint strain, bruises) or tendonitis (inflammation of tendons),

Only adults (over 18 years):

- or more than 3 weeks in case of arthrosis.

The medicine may be used for an extended period only if advised by your doctor.

Tell your doctor if the pain and swelling do not improve or worsen within 7 days.

If you take more Voltaren Emulgel than you should

- If you have used more than you should, wipe off the excess gel with an absorbent paper towel.
- Contact your doctor immediately if you or your child accidentally swallows the medicine.

If you forget to use Voltaren Emulgel

If you forget to apply Voltaren Emulgel, apply it as soon as you remember and continue as usual. Do not administer a double dose to make up for a forgotten dose.

If you have any 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 can be serious.

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

- Skin rash with blisters, urticaria (may affect 1 to 10 of 10,000 persons).
- Rapid breathing, shortness of breath or tightness in the chest (asthma) (may affect less than 1 of 10,000 persons).
- Swelling of the face, tongue or throat (may affect less than 1 of 10,000 persons).

Other side effects that may occur are usually mild, harmless and self-limiting. If you are concerned, tell your doctor or pharmacist as soon as possible.

Common side effects (may affect 1 to 10 of 100 persons)

- Skin rash, itching, redness or pricking sensation.

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

- The skin may be more sensitive to sunlight. Possible signs include sunburn with itching, swelling 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 this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help 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 11.6 mg of diclofenac diethylamine, corresponding to 10 mg of diclofenac sodium.
- The excipients are: carbomer, macrogol, cetostearyl ether, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, propylene glycol, liquid paraffin, perfume composition 45 (contains benzyl benzoate), purified water.

What Voltaren Emulgel looks like and contents of the pack

Voltaren Emulgel is a white to whitish, cooling, non-greasy, non-staining, creamy gel.

Pack size:

20 g or 50 g of gel in a membrane-sealed aluminium tube.

20 g, 50 g, 75 g, 100 g or 150 g of gel in an aluminium laminated tube. An applicator pack is also available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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