

Voltarol 1.16% Emulgel gel

Diclofenac diethylammonium



Patient Information Leaflet

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

Voltarol Emulgel contains the active substance diclofenac which belongs to a group of medicines called non-steroidal antiinflammatory drugs (NSAIDs). It is specially formulated for rubbing into the skin and used to relieve pain and reduce inflammation and swelling in painful conditions affecting the joints and muscles.

Voltarol Emulgel can be used to treat:

- muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries)
- tendonitis (e.g. tennis elbow)
- osteoarthritis.

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

DO NOT use Voltarol Emulgel if you:

- are in the last 3 months of your pregnancy (see also pregnancy and breast-feeding section)
- have an allergy (hypersensitivity) to any of the ingredients in the product (see Section 6 'What Voltarol Emulgel contains').
- have ever had an allergic reaction to diclofenac or other medicines used to treat 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 hives; swelling of the face or tongue; runny nose.

This medicine is not recommended for use in children under 14 years of age.

Take special care with Voltarol Emulgel

- Do not apply the gel to skin that has (i) a rash or eczema (ii) cuts or open wounds. Stop the treatment if a skin rash develops after applying the product.
- Avoid applying on large areas of skin and over a prolonged period of time, unless under medical advice.
- Due to an increased possibility of side effects, take care if you are using any other medicine containing diclofenac or painkillers known as NSAIDs, such as aspirin or ibuprofen.
- Be careful when sunbathing or using sun lamps as your skin may be more sensitive to sunlight.
- If you have a stomach or duodenal ulcer

(or a history of), tell your doctor or pharmacist before using the gel.

- Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including those obtained without a 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 or pharmacist for advice before taking this medicine.

Voltarol Emulgel must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. Voltarol Emulgel should only be used under medical advice during the first 6 months of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

Voltarol Emulgel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Voltarol Emulgel should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period of time.

Consult your doctor or pharmacist for further information if you are pregnant or breast-feeding.

Driving and using machines

Voltarol Emulgel, when used as directed, is not expected to have any effect on your ability to drive or use machines.

Important information about some of the ingredients of Voltarol Emulgel

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

3. How to use Voltarol Emulgel

- Always use Voltarol Emulgel exactly as your doctor has told you.
- The gel is only for use on your skin. Do not use it in your mouth. Inform your doctor immediately in case of accidental swallowing.
- Do not put Voltarol Emulgel in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.

Adults

1. Take the tube out of the carton:
 - a. For the aluminium tube: Before first use, pierce the sealing membrane of the tube with the spiked top of the cap. Do not use if seal is broken
 - b. For the laminated tube: Unscrew and remove cap. When using for the first time, reverse the cap, engage with the nozzle, twist and remove the seal from the tube. Do not use if seal is broken.
2. Gently squeeze out a small amount of gel from the tube and apply to the painful or swollen area 3 to 4 times a day, slowly rubbing into the skin.

- The amount needed will vary depending on the size of the painful or swollen area; an amount ranging in size from a 1 penny to a 2 pence piece will usually be sufficient. You may notice a slight cooling effect when you rub the gel in.
3. Do not rub the gel into cuts, open wounds or any other area where the skin is abnormal. After rubbing the gel into the skin, do not cover with bandages or sticking plaster.
 4. Be careful not to get the gel in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.
 5. Wash your hands after rubbing in Voltarol Emulgel, unless your hands are the site being treated. Replace the cap.
 6. Allow at least four hours between applications of the gel. Do not apply more than 4 times in any 24 hour period.

This medicine is not recommended for use in children under 14 years of age.

Do not use Voltarol Emulgel for more than:

- 2 weeks for muscle and joints injuries (e.g. sprains, strains, bruises) or tendonitis.
- If you are using the gel for arthritis, your doctor may wish to review your treatment regularly.

If symptoms do not improve within this time, or they get worse, consult your doctor. In children aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

If you use more Voltarol Emulgel than you should

If you or a child accidentally swallows Voltarol Emulgel, contact your doctor or accident and emergency department immediately.

If you forget to use Voltarol Emulgel

If you miss your application of Voltarol Emulgel at the correct time, apply it as soon as you remember then carry on as normal. Do not apply a double quantity to make up for a forgotten application. If you have any further questions on the use of this product, ask your pharmacist.

4. Possible side effects

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

Some rare and very rare side effects might be serious

If you experience any of the following signs of allergy, STOP using Voltarol Emulgel and tell a doctor or pharmacist immediately:

Skin rash with blisters; hives (may affect between 1 and 10 in every 10,000 people).

Wheezing, shortness of breath or feeling of tightness in the chest (asthma) (may affect less than 1 in every 10,000 people).

Swelling of the face, lips, tongue or throat (may affect less than 1 in every 10,000 people).

Other side effects which may occur are usually mild, passing and harmless (if you are concerned, tell a doctor or pharmacist).

Common side effects (may affect between 1 and 10 in every 100 people)

Skin rash, itching, reddening or smarting of the skin

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

The skin may be more sensitive to the sun.

Possible signs are sunburn with itching, swelling and blistering.

Some side effects have unknown frequency (*cannot be estimated from available information*): local application site irritation, peeling of the skin and skin discolouration.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Voltarol Emulgel

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not use Voltarol Emulgel after the expiry date stated on the carton and tube. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Voltarol Emulgel contains

The **active substance** is diclofenac diethylammonium (1.16%) equivalent to 1 g of diclofenac sodium in each 100 g of gel in the 100 g tube and 0.2 g of diclofenac sodium in each 20 g of gel in the 20 g tube.

The **other ingredients** are diethylamine, carbomers, macrogol cetostearyl ether, cocoyl caprylocaprate, isopropyl alcohol, propylene glycol, liquid paraffin, perfume creme 45 (contains benzyl benzoate), purified water (see end of Section 2 'Important information about some of the ingredients of Voltarol Emulgel' for propylene glycol and benzyl benzoate).

What Voltarol Emulgel looks like and contents of the pack

Voltarol Emulgel is a white, cooling, non-greasy, non-staining cream-like gel, packed inside an aluminium tube or aluminium laminated tube with plastic screw cap. This is supplied in a carton and comes in packs of 20 g and 100 g.

Marketing authorisation holder and Manufacturer:

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

This leaflet was last revised in March 2020.

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