

Package leaflet: Information for the user

Voltarol® Emulgel® 1% w/w Gel

diclofenac diethylammonium

diclofenac diethylammonium 1.16% w/w corresponding to diclofenac sodium 1% w/w

For joint, back and muscular pain relief

Relieves pain, reduces inflammation, cooling effect

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

This medicine is available without prescription. However, you still need to use Voltarol Emulgel 1% w/w Gel carefully to get the best results from it.

- Keep this leaflet. You may need to read it again. Note that this leaflet is revised on a regular basis with the latest information on your medicine. Please refer to the date at the end of this leaflet.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve within 7 days.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

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1. What Voltarol Emulgel 1% w/w Gel is and what it is used for

Voltarol Emulgel 1% w/w Gel contains the active ingredient diclofenac which is from the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Voltarol Emulgel 1% w/w Gel is used in adults, the elderly and adolescents aged 14 years and over to relieve pain and reduce swelling in a number of painful conditions affecting the joints and muscles, e.g. sprains, strains and bruises. It is also used to relieve the pain of muscular rheumatism.

2. What you need to know before you use Voltarol Emulgel 1% w/w Gel

DO NOT use Voltarol Emulgel 1% w/w Gel if you:

- are allergic (hypersensitive) to diclofenac, propylene glycol, benzyl benzoate, isopropyl alcohol or any of the other ingredients in the product (see Section 6)
- have ever had an allergic reaction to diclofenac or other medicines used to treat pain, fever or inflammation, such as ibuprofen or aspirin. 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
- are asthmatic and are allergic (hypersensitive) to aspirin or other non-steroidal agents, such as ibuprofen
- are in the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.
- are below 14 years of age.

Take special care with Voltarol Emulgel 1% w/w Gel

- Do NOT apply to skin with conditions such as cuts, open wounds, or on skin that has a rash or eczema.
- The gel can be used with a permeable (non-occlusive) bandage. Do not use an airtight occlusive dressing.
- Discontinue the treatment if a skin rash develops after applying the product.
- This gel is for use only on the skin. Do not use it in the mouth. Do not swallow it. Be careful not to get the gel in your eyes or the inside of your nose. If you get the gel in your

eyes, rinse them well with clean water. See your doctor or pharmacist if any discomfort persists.

- Avoid applying on large areas of skin and over a prolonged period of time, unless under medical advice. Use of the gel over extensive areas of skin for a prolonged time or using more than the recommended dose may give some side effects. Symptoms include: gastrointestinal disturbances and bleeding, irritability, fluid retention, rash, liver inflammation, kidney problems, allergic reactions, difficulty in breathing and skin lesions.
- Your skin may be more sensitive to sunlight. Be careful when sunbathing or using sun lamps.
- If you have, or have had, peptic ulcers, gastrointestinal bleeding, liver or kidney problems, certain blood disorders, asthma or intestinal inflammation, tell your doctor or pharmacist.
- 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 1% w/w Gel 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 1% w/w Gel 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 1% w/w Gel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Voltarol Emulgel 1% w/w Gel 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 1% w/w Gel, 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 1% w/w Gel

Voltarol Emulgel 1% w/w Gel contains **propylene glycol** and **benzyl benzoate**, which may cause skin irritation.

3. How to use Voltarol Emulgel 1% w/w Gel

Always use this medicine exactly as described in this leaflet or as advised by your doctor or pharmacist. The gel is for use only on the skin.

Adults and adolescents 14 years and over:

1. Before using for the first time, open as follows:
Reverse the cap, engage with the nozzle, twist and remove the seal from the tube.
2. Gently rub a small amount of gel into the skin around the painful or swollen area. The amount of gel needed will vary depending upon the size of the painful or swollen area. Usually, a quantity the size of a cherry or a walnut will be sufficient.
3. You can apply the gel 3 to 4 times a day unless your doctor or pharmacist tells you otherwise. You may notice a slight cooling effect when you rub the gel into the skin. 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.
- Be careful not to get the gel in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.
- Wash your hands after rubbing in the gel (unless they are the site being treated).

For tube with no mess applicator:



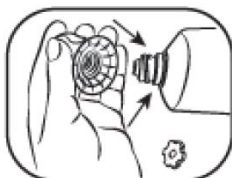
1. Pull off the transparent protective cover



2. Unscrew the applicator cap



3. Using the key on the applicator cap to remove the star seal on the tube



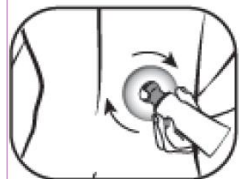
4. Screw the applicator cap back on the tube



5. Pull white part to open



6. Squeeze the tube to release required amount of Emulgel



7. Apply to skin, closing cap on application



8. Clean the applicator with cotton towel or absorbent paper until visually dry and clean

This medicine must not be used in children under 14 years of age

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.

Do not use Voltarol Emulgel 1% w/w Gel for more than 7 days.

If you use more Voltarol Emulgel 1% w/w Gel than you should

If you use more Voltarol Emulgel 1% w/w Gel than you should, wipe off the surplus gel with a tissue.

If you or a child accidentally swallows Voltarol Emulgel 1% w/w Gel, contact your doctor or accident and emergency department immediately.

If you forget to use Voltarol Emulgel 1% w/w Gel

If you miss your application of Voltarol Emulgel 1% w/w Gel 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 1% w/w Gel 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 1% w/w Gel 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*)

Rash with pustule, the skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering.

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 this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Voltarol Emulgel 1% w/w Gel

Keep this medicine out of the sight and reach of children.

Do not store above 30 °C. Keep the tube in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month. After first opening use within 16 weeks.

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 Voltarol Emulgel 1% w/w Gel contains

The **active substance** is diclofenac diethylammonium (equivalent to 1 g of diclofenac sodium in each 100 g of gel).

The **other ingredients** are diethylamine, Carbomer 974 P, cetomacrogol, cocoyl caprylocaprate, isopropyl alcohol, liquid paraffin, propylene glycol, purified water, perfume crème (containing benzyl benzoate) (for further information on propylene glycol and benzyl benzoate see end of Section 2 'Important information about some of the ingredients of Voltarol Emulgel 1% w/w Gel').

What Voltarol Emulgel 1% w/w Gel looks like and contents of the pack

Voltarol Emulgel 1% w/w Gel is a white to slightly milky gel, packed inside a tube with a plastic screw cap. This is supplied in a carton and comes in packs of 50 g and 100 g. Not all pack sizes may be marketed.

Manufacturer

GlaxoSmithKline Consumer Healthcare GmbH & Co. KG, Barthstraße 4, 80339 Munich, Germany.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

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