

VOLTAREN EMULGEL[®]

Diclofenac Diethylamine (1%w/w)

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What Voltaren Emulgel is used for

Voltaren Emulgel 1% contains the active substance diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is specially formulated for rubbing into the skin.

Voltaren Emulgel 1% is used to relieve pain and reduce inflammation and swelling in a number of painful conditions affecting the joints and muscles. It can be used to treat:

- Muscle, joints, tendons, ligaments injuries (e.g. sprains, strains, bruises, backache, sports injuries);
- tendonitis (e.g. tennis elbow);
- mild arthritis of the knee or fingers.

How Voltaren Emulgel works

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) with pronounced analgesic, anti-inflammatory and antipyretic properties. Inhibition of prostaglandin synthesis is the primary mechanism of action of diclofenac.

Voltaren Emulgel is an anti-inflammatory and analgesic preparation designed for topical application. In inflammation and

pain of traumatic or rheumatic origin.

Voltaren Emulgel relieves pain and decreases swelling.

Before you use Voltaren Emulgel

- When you must not use it

- If you are allergic (hypersensitive) to diclofenac or other medicines used to treat pain, fever or inflammation, such as ibuprofen or acetylsalicylic acid (a substance also used to prevent blood clotting), or any of the other ingredients of Voltaren Emulgel 1% listed at the end of this leaflet. If you are not sure, ask your doctor or pharmacist. Symptoms of an allergic reaction to these medicines may include: wheezing or shortness of breath (asthma); skin rash with blisters or hives; swelling of the face or tongue; runny nose.
- If you are in the last 3 months of pregnancy.

If any of these applies to you, do not use Voltaren Emulgel 1%.

Important information about some of the ingredients of Voltaren Emulgel

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

Pregnancy and breast-feeding

- Do not use Voltaren Emulgel 1% if you are pregnant, especially during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.
- Do not use Voltaren Emulgel 1% if you are breast-feeding.
- Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

- Do not apply to skin with conditions such as cuts, open wounds, or on skin that has a rash or eczema.
- Voltaren Emulgel 1% is for external use only. Do not use it in the mouth. Do not swallow it. Be careful not to get Voltaren Emulgel 1% in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.
- A brace or wrap commonly used for injuries like sprains can be used but do not use under airtight (plastic) bandages.

If you have any questions, talk to your doctor or pharmacist before using Voltaren Emulgel 1%

Children and adolescents

Do not use Voltaren Emulgel 1% on a child under 12 years of age.

- 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 medical prescription.

How to use Voltaren Emulgel

- How much to use

Apply Voltaren Emulgel 1% 3 to 4 times a day on the painful area.

- When to use it

1. To remove the seal before first use, unscrew and remove the cap. Use the reverse side of the cap to insert, twist and remove the seal from the tube.
2. Gently squeeze out a small amount of gel from the tube and apply to the painful or swollen area, slowly rubbing into the skin. The amount needed will vary depending upon the size of the painful or swollen area; an amount ranging in size from a cherry

to a walnut will usually be sufficient. You may notice a slight cooling effect when you rub the gel in.

3. Wash your hands after rubbing in Voltaren Emulgel 1%, unless of course they are the site being treated.

- How long to use Voltaren Emulgel

Do not use Voltaren Emulgel 1% for more than:

- 2 weeks

Longer treatment may be recommended by a doctor.

- If you forget to use it

If you miss your application of Voltaren Emulgel 1% at the correct time, apply it when you remember and then carry on as normal. Do not apply a double quantity to make up for the forgotten application.

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

If you use too much (overdose)

In case you or a child accidentally swallows Voltaren Emulgel 1%, or in case you have accidentally used much more than recommended, contact your doctor immediately.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

- Things you must not do

- Do not apply to skin with conditions such as cuts, open wounds, or on skin that has a rash or eczema.
- Voltaren Emulgel 1% is for external use only. Do not use it in the mouth. Do not swallow it. Be careful not to get Voltaren Emulgel 1% in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.

- A brace or wrap commonly used for injuries like sprains can be used but do not use under airtight (plastic) bandages.

- Things to be careful of

Driving and using machines

Voltaren is unlikely to affect the ability to drive, use machines or carry out other activities that need careful attention.

Side effects

Like all medicines, Voltaren Emulgel 1% can cause side effects, although not everybody gets them.

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

- Skin rash with blisters; hives.
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma).
- Swelling of the face, lips, tongue or throat.

Other side effects which may occur are usually mild, passing and harmless

Common side effects

Skin rash, itching, reddening or smarting of the skin

Very rare side effects

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

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of Voltaren Emulgel

- Storage

- Keep this medicines out of the reach and sight of children.
 - Do not store above 30°C
 - Do not use Voltaren Emulgel after the expiry date which is stated on the outer pack and on the immediate container. The expiry date refers to the last day of that month.
 - Store in the original package.
- Disposal**
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer used. These measures will help to protect the environment.

Product Description

- What it looks like

Voltaren Emulgel 1% is a white to practically white, cooling, non-greasy, non-staining cream-like gel.

Pack size(s): 10g, 20g, 30g, 50g.

Not all pack sizes may be marketed.

Ingredients

- Active ingredients

The **active substance** is diclofenac diethylamine. One gram of gel contains 11.6 mg of diclofenac diethylamine, which corresponds to 10mg of diclofenac sodium.

- Inactive ingredients

The other ingredients are carbomer, cetomacrogol 1000 ether, cetiol LC, diethylamine, isopropyl alcohol, propylene glycol, liquid paraffin, perfume (containing benzyl benzoate), and purified water.

Information might differ in some countries.

MAL Number

Voltaren Emulgel 1%:
MAL19991357ARZ (First source)
MAL05032552ARSZ (Second source)

Manufacturer

First source:

Novartis Pharma Produktions
GmbH
Orlinger Strasse 44,
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Second source:

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Product Registration Holder

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