

VOLTAREN 12 HOURS EMULGEL 2% GEL

Diclofenac diethylamine (23.2mg/g)

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What Voltaren 12 Hours Emulgel 2% Gel is used for

Voltaren 12 Hours Emulgel 2% Gel 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 and joints injuries (e.g. sprains, strains, bruises, backache, sports injuries);
- tendonitis (e.g. tennis elbow), swelling around elbow or knee;
- mild arthritis of the knee or fingers. Voltaren 12 Hours Emulgel 2% Gel is intended for use in adults and adolescents aged 12 years and older.

How Voltaren 12 Hours Emulgel 2% Gel works

Voltaren 12 Hours Emulgel 2% Gel contains the active substance diclofenac, which is a non-steroidal anti-inflammatory drug (NSAID). It is specially formulated for rubbing into the skin.

Before you use Voltaren 12 Hours Emulgel 2% Gel

- When you must not use it

Do not use Voltaren 12 Hours Emulgel 2% Gel if

- you are allergic (hypersensitive) to diclofenac or other non-steroidal anti-inflammatory medicines used to treat pain, fever or inflammation, such as ibuprofen or aspirin (a substance also used to prevent blood clotting), or any of the other ingredients of this medicine. If you are not sure, ask your doctor

or pharmacist. Symptoms of an allergic reaction may include: wheezing or shortness of breath (asthma); skin rash with blisters or hives; swelling of the face or tongue; runny nose.

- you are in the last 3 months of pregnancy.

Important information about some of the ingredients of Voltaren 12 Hours Emulgel 2% Gel

The gel formulation contains propylene glycol, which may cause mild localised skin irritation in some people, and butylhydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

Children

Do not use Voltaren 12 Hours Emulgel 2% Gel in children under 12 years of age.

Pregnancy and breast-feeding

Use only on advice of your doctor if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. Do not use Voltaren 12 Hours Emulgel 2% Gel if you are in the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

- Before you start to use it

If you have any questions, talk to your doctor or pharmacist before using Voltaren 12 Hours Emulgel 2% Gel.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any regular medication on prescription or over the counter products.

How to use Voltaren 12 Hours Emulgel 2% Gel

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. Squeeze out a small amount of gel from the tube and gently rub into the skin where you have pain or swelling. You may notice a slight cooling effect when you rub the gel in.

3. Wash your hands after rubbing in Voltaren 12 Hours Emulgel 2% Gel unless of course they are the site being treated.

- How much to use

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.

- When to use it

Apply Voltaren 12 Hours Emulgel 2% Gel 2 times a day (morning and evening) on the painful area.

- How long to use it

Do not use Voltaren 12 Hours Emulgel 2% Gel for more than 2 weeks. Use no more than is required for shortest period of time needed. If the pain and swelling does not improve within 7 days, or if they get worse, tell your doctor. Longer treatment may be recommended by a doctor.

- If you forget to use it

If you miss your application of Voltaren 12 Hours Emulgel 2% Gel 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 use too much (overdose)

If you use more gel than you should, wipe off the surplus gel with a tissue. If you or a child accidentally swallows the gel, seek medical advice immediately.

While you are using it

- Things you must do

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

- 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. Discontinue the treatment if a skin rash develops after applying the product.
- Do not use more product than directed or for a longer period of time than directed, unless told by your doctor.

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- Voltaren 12 Hours Emulgel 2% Gel is for topical use only. Do not use it in the mouth. Do not swallow it. Be careful not to get Voltaren 12 Hours Emulgel 2% Gel 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

- Voltaren 12 Hours Emulgel 2% Gel is unlikely to affect the ability to drive, use machines or carry out other activities that need careful attention.
- Be cautious when smoking or near naked flames due to risk of severe burns. Voltaren 12 Hours Emulgel 2% Gel contains paraffin which is potentially flammable when it builds up on fabric (clothing, bedding, dressings etc.) and may not be totally removed by laundering.

Side Effects

When using this product you may experience:

- Skin rash with or without blisters; hives; wheezing, shortness of breath or feeling of tightness in the chest (asthma); swelling of the face, lips, tongue or throat; itching or reddening of the skin.
- The skin may be more sensitive to sunlight (sun or tanning booth). Possible signs are sunburn with itching, swelling and blistering.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Voltaren 12 Hours Emulgel 2% Gel- Storage

- Keep this medicine out of the reach and sight of children.
- Do not use Voltaren 12 Hours Emulgel 2% Gel after the expiry date which is stated on the carton and tube after EXP.

- Do not store above 30°C.

- Disposal

- Any unused product or waste material should be disposed of in accordance with local requirements.

Product Description- What it looks like

Voltaren 12 Hours Emulgel 2% Gel is a white to practically white, soft, homogeneous, cream-like gel. The product comes in packs of 30g, 50g. Not all pack sizes may be marketed.

- Ingredients

- Active ingredients

The active substance is diclofenac diethylamine. Each gram of gel contains 23.2 mg (2.32% w/w) of diclofenac diethylamine, which corresponds to 20 mg (2% w/w) of diclofenac sodium.

- Inactive ingredients

The other ingredients (excipients) are butylhydroxytoluene, carbomer, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, liquid paraffin, macrogol cetostearyl ether, oleyl alcohol, propylene glycol, perfume eucalyptus sting, and purified water.

- MAL number:

MAL16065024ARZ

Manufacturer

Haleon CH SARL
Route de l'Etraz
CH-1260 Nyon
Switzerland.

Product Registration Holder

Haleon Malaysia Sdn. Bhd.
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Date of Revision

03/01/2025

Serial Number

NPRA(R1/5)1122022/318