

PACKAGE LEAFLET: INFORMATION FOR THE USER

Voltaren Emulgel 1%

10 mg / g Gel

DICLOFENAC

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine 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 signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What VOLTAREN EMULGEL 1% tablets is and what it is used for
2. Before you take VOLTAREN EMULGEL 1%
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1. WHAT VOLTAREN EMULGEL 1% IS AND WHAT IT IS USED FOR

VOLTAREN EMULGEL 1% contains a substance called diclofenac which is one of the group of medicines called non-steroidal antiinflammatory analgesics, used to relieve pain and reduce swelling in a number of painful conditions affecting the joints and muscles. It is specially formulated for rubbing into the skin and is used to relieve pain and reduce inflammation and swelling in painful conditions affecting the joints and muscles:

- muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries)
- localized forms of soft tissue rheumatism: tendonitis (e.g. tennis elbow), bursitis, shoulder-arm syndrome and peri-arthritis (joint disease)
- moderate forms of arthritis (inflammation of the joints) of the knee or fingers.

2. BEFORE YOU TAKE VOLTAREN EMULGEL 1%

Do not take VOLTAREN EMULGEL 1%

- If you are allergic to any of the ingredients in the product (see Section 6). If you 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.

- if you are in the last 3 months of your pregnancy

Take special care with Voltaren Emulgel 1%

- Do not apply the gel to skin that has a rash or eczema, cuts or open wounds. Stop the treatment if a skin rash develops after applying the product.

Be careful not to get Voltaren Emulgel in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.

Children and adolescents

Do not use Voltaren Emulgel in children below 12 years of age.

Taking other medicines

Tell your doctor or pharmacist about any other medicines you are taking, or have recently taken, including any you have bought without a medical prescription.

In local application of the gel such interactions are very unlikely due to the very low systemic absorption of diclofenac.

Pregnancy and breastfeeding

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 any medicine.

Voltaren Emulgel must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. Voltaren 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.

Voltaren Emulgel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Voltaren Emulgel should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin for a prolonged period of time. Consult your doctor or pharmacist for further information if you are pregnant or breastfeeding.

Driving and using machines

Voltaren 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 Voltaren Emulgel

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

3. HOW TO TAKE VOLTAREN EMULGEL 1%

Always take VOLTAREN EMULGEL 1% exactly as you are told by your doctor. If you are unsure, check with your doctor or pharmacist.

For adults and adolescents over 12 years of age

Gently rub a small amount of Voltaren Emulgel 3 to 4 times daily into the skin where you have pain or swelling. The amount needed depends on the size of the affected area.

Before first use, pierce the sealing membrane of the tube with the spiked top of the cap.

Do not use if seal is broken.

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; usually, an amount ranging in size from a cherry to a walnut will be enough.
Wash your hands after the application, unless of course they are the site being treated.

How long should I use VOLTAREN EMULGEL 1% gel?

The length of treatment is determined by the doctor.

- 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 take more VOLTAREN EMULGEL 1% than you should

If you have used too much VOLTAREN EMULGEL 1% gel, tell your doctor. Overdose is very unlikely because diclofenac in Voltaren Emulgel 1% is very poorly absorbed through the skin.

Contact your doctor immediately if you find you have accidentally used more Voltaren Emulgel than recommended, or in case of accidental ingestion.

If you forget to take VOLTAREN EMULGEL 1%

If you miss your application of Voltaren Emulgel 1% 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.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, VOLTAREN EMULGEL 1% 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 an allergy, STOP using Voltaren Emulgel 1% and tell your 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 (if you are concerned, tell your doctor or pharmacist).

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.

5. HOW TO STORE VOLTAREN EMULGEL 1%

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use VOLTAREN EMULGEL 1% after the expiry date which is stated on the on the tube and the folding box, 3 years from the date of manufacture.

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 VOLTAREN EMULGEL 1% contains

The active ingredient is diclofenac diethylamine.

1 g of gel contains 11.6 mg of diclofenac diethylamine, corresponding to 10 mg of diclofenac sodium.

Excipients: carbomer, macrogol cetostearyl ether, cocoyl-caprylocaprato, diethylamine, isopropyl alcohol, liquid paraffin, perfumed cream 45, propylene glycol and purified water.

What VOLTAREN EMULGEL 1% looks like and contents of the pack

50 g of gel in an aluminum tube, in a cardboard box.

Regime of dispensing

The medicine is issued without a doctor's prescription.

Manufacturer

NOVARTIS CONSUMER HEALTH SA, ROUTE DE L'ETRAZ, 1260 NYON, SWITZERLAND

Manufacturer of the medicinal product

NOVARTIS PHARMA PRODUKTIONS GMBH, OETLINGERSTRASSE 44, WEHR, GERMANY