

Voltaren 1% Emulgel



Information for patients

Read this leaflet carefully. You will find all the important information about the drug. This medicine has been prescribed by your doctor or was given to you without prescription by the pharmacist or druggist. To get the greatest benefit, please use it according to the package leaflet or, if appropriate, according to the indications of the doctor, pharmacist or druggist. Keep this leaflet in order to read it again later if necessary.

What is Voltaren Emulgel and when is it used?

Voltaren Emulgel contains the active ingredient diclofenac, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs.

Voltaren Emulgel has analgesic and anti-inflammatory properties and has, thanks to the aqueous-alcoholic base, a soothing and cooling effect.

Voltaren Emulgel is used for the Topical treatment of pain, inflammation and swelling in:

- 1- injuries to tendons, ligaments, muscles and joints, e.g., sprains, contusions, muscle strains or back pain following sporting activity or an accident,
- 2- localized forms of extra-articular rheumatism, e.g., tendinitis (tennis elbow), shoulder-hand syndrome, bursitis, peri arthropathies,
- 3- For the symptomatic treatment of osteoarthritis of the small and medium superficial joints, e.g., finger or knee joints.

Voltaren Emulgel is intended for use in adults and adolescents aged 12 years and above.

When should Voltaren Emulgel not be used?

Voltaren Emulgel should not be used in cases of hypersensitivity to the active substance diclofenac or other analgesic and anti-inflammatory agents (especially acetylsalicylic acid and ibuprofen) and in case of hypersensitivity to propylene glycol, isopropyl alcohol or other excipients.

Such hypersensitivity is expressed for example by shortness of breath (asthma), difficulty breathing, skin rash, urticaria, swelling of the face and tongue, rhinorrhea (runny nose). Voltaren Emulgel should not be used during the last three months of pregnancy.

What precautions should be considered when using Voltaren Emulgel?

Voltaren Emulgel must not be applied on open wounds (e.g. grazes, cuts) or on damaged skin (e.g. eczema, skin rash). Do not use more product than directed for a longer period. A brace or wrap commonly used for injuries like sprains can be used, but do not use under airtight (plastic) bandages.

Avoid contact with eyes and mucous membranes.

If contact occurs, rinse the eyes thoroughly with running water. Tell your doctor if problems persist.

If you accidentally swallow the Emulgel or if a child does, contact your doctor immediately.

Because of the propylene glycol or benzyl benzoate contained in Voltaren Emulgel, some patients may develop mild, localized skin irritation.

Inform your doctor, your pharmacist or your druggist if you have had allergic reactions after the use of similar products (antirheumatic ointments), if you have another illness, you are allergic, you are taking or are already using other medicines for internal or external usage (including self-medication).

Can Voltaren Emulgel be used during pregnancy or breastfeeding?

Pregnancy:

Voltaren Emulgel must not be used during the first or second trimester of pregnancy or during breastfeeding unless prescribed by your doctor.

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

If you are planning to become pregnant, you should ask your doctor, pharmacist or chemist for advice before use.

How to use Voltaren Emulgel?

The product is for external use only.

Adults and children from 12 years.

Depending on the size of the painful or swollen area or surfaces to be treated, rub gently into the skin, an amount of 2-4 g enough to treat an area of about 400-800 cm² of Voltaren Emulgel (cherry to walnut sized amount)

3 to 4 times a day. Wash hands after application, unless they are the site being treated.

After application:

- 1- Wipe your hands with a dry paper towel, then wash them thoroughly, unless the fingers are being treated. Dispose of the paper towel with the household waste.
- 2- You must wait for the Emulgel to dry on your skin before taking a shower or a bath.

If you miss a treatment with Voltaren Emulgel, apply the treatment as soon as possible and then go on with the normal treatment. Do not apply the double amount at once to make up for the forgotten treatment.

Inform your doctor if the symptoms worsen or if the symptoms have not improved after one week. Voltaren Emulgel should not be used longer than 2 weeks without medical prescription.

Use the product for the shortest time possible and do not apply more than necessary.

Children under 12 years

The use and safety of Voltaren Emulgel have not yet been established for children under 12 years of age and its use is therefore not recommended in this age group.

If an adult or a child (accidentally) swallows Voltaren Emulgel, seek immediate medical attention.

Use the dose shown in this package leaflet or as prescribed by your doctor. If you think that the effect of the medicine is too weak or too strong, tell your doctor or pharmacist.

What side effects can Voltaren Emulgel have?

The use of Voltaren Emulgel can cause the following side effects.

The frequency could vary from common, rare, to very rare. If any of the following side effects occur, stop immediately the treatment with Voltaren Emulgel and inform your doctor:

- skin rash with blisters, urticaria
- wheezing, shortness of breath or a feeling of tightness in the chest (asthma)
- swelling of the face, lips, tongue and throat.

The following side effects are generally mild and temporary:

- 1- *Common (occurring in 1 to 10 out of 100 users):* skin rash, itching, redness, a sensation of burning on the skin.
 - 2- *Very rare (occurring in fewer than 1 out of 10,000 users):* increased skin sensitivity to the sun. The symptoms of such skin sensitization are itchy sunburn, swelling of the skin and blistering.
- If you notice any side effects, tell your doctor, pharmacist.

This applies particularly to side effects not mentioned in this leaflet.

What else should be taken into account?

Don't store above 30°C and keep away from sun.

The drug should not be used beyond the date indicated after "EXP" on the container.

Keep drugs out of the reach of children.

Further information can be obtained from your doctor, pharmacist or druggist. These people have the detailed information for professionals.

Do not dispose of any medicines in the sewers (e.g. do not throw them down the toilet or sink). This helps to protect the environment.

What does Voltaren Emulgel contain?

100 g of Voltaren Emulgel contains:

Active ingredient:

1.16 g of diclofenac diethylamine corresponding to 1 g of diclofenac sodium.

Excipients:

Carbomer, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, macrogol cetostearyl ether, paraffin wax, propylene glycol, fragrance (containing benzyl benzoate), purified water.

Where do you get Voltaren Emulgel?

What packages are available on the market?

In pharmacies and drugstores, without prescription.

Tubes of 100 gm, 50 gm and 20 gm.

Not all the packages are available in all countries.

Manufactured by: GSK Consumer Healthcare SARM, Nyon, Switzerland.

MAH: GSK Consumer Healthcare Schweiz AG, Switzerland.

Trademarks owned or licensed by GSK



This leaflet has been revised in June 2021 -GDSV4 based on country of origin leaflet dated October 2020

(THIS IS A MEDICAMENT)

- a) Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- b) Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- c) The doctor and the pharmacist are experts in medicine, its benefits and risks.
- d) Do not by yourself interrupt the period of treatment prescribed.
- e) Do not repeat the same prescription without consulting your doctor.
Keep medicament out of reach of children
Council of Arab Health Ministers
Union of Arab Pharmacists