

Voltaren®

12 Emulgel 12 Hours

Diclofenac diethylamine



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

Always use Voltaren Emulgel 12 Hours exactly as described in this leaflet, or as your pharmacist has told you. You should check with your doctor or pharmacist, if you are not sure.

- This medicine is available without prescription. However, you still need to use Voltaren Emulgel 12 Hours carefully to get the best results from it. 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 the leaflet.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist, if you need more information or advice.
- You must contact a doctor, if your signs of illness worsen or do not improve after 7 days.
- If you get any side effects which worry you (even side effects not listed in this leaflet), talk to your doctor or pharmacist.

This leaflet contains the following information:

1. What Voltaren Emulgel 12 Hours is and what it is used for
2. What you need to know about Voltaren Emulgel 12 Hours
3. How to use Voltaren Emulgel 12 Hours
4. Possible side effects
5. How to store Voltaren Emulgel 12 Hours
6. What the pack contains and further information

1. What Voltaren Emulgel 12 Hours is and what it is used for

Voltaren Emulgel 12 Hours 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 and has enhanced skin permeation.

Voltaren Emulgel 12 Hours is used to relieve pain and reduce inflammation and swelling in a number of painful conditions affecting the joints and muscles.

Voltaren Emulgel 12 Hours can be used to treat:

- Injuries to tendons, ligaments, muscles and joints, such as sprains, bruises, strains or back pain as a result of sports or accidents
- localized forms of rheumatism not involving joints, such as tendonitis (tennis elbow), shoulder-hand syndrome, bursitis, periarthritis
- and for symptomatic treatment of osteoarthritis of small and medium-sized joints close to the skin, such as the joints of the fingers or knees.
- **Voltaren Emulgel 12 Hours** is intended for use in adults and adolescents aged 12 years and older.

2. What you need to know about Voltaren Emulgel 12 Hours

Do not use Voltaren Emulgel 12 Hours 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 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) breathing difficulties
- Skin rash with blisters or hives
- Swelling of the face or tongue
- Runny nose

If any of these apply to you, do not use Voltaren Emulgel 12 Hours. If the pain and swelling do not improve within 7 days, or if they get worse, tell your doctor.

- **Voltaren Emulgel 12 Hours** should not be used during the last 3 months of pregnancy (also see "Using **Voltaren Emulgel 12 Hours** during pregnancy and breast-feeding").

If you use more Voltaren Emulgel 12 Hours than you should:

- If you use more gel than you should, wipe off the surplus gel with a tissue.

If you forget to use Voltaren Emulgel 12 Hours:

If you miss your application of Voltaren Emulgel 12 Hours 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.

3. How to use Voltaren Emulgel 12 Hours

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

How much Voltaren Emulgel 12 Hours to use for adults and adolescents over 12 years of age

Apply Voltaren Emulgel 12 Hours 2 times a day (morning and evening) on the painful area, which provides lasting pain relief up to 12 hours.

Children under 12 years of age

Using Voltaren Emulgel 12 Hours in children under 12 years of age has not been established to be safe. Therefore, using it in this age group is not recommended.

How to apply Voltaren Emulgel 12 Hours

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 gently rub on the affected area. The amount needed depends on the size of the painful area: 2 g to 4 g (a quantity ranging in size from a cherry to a walnut) of gel is sufficient to treat an area of about 400-800 cm².
3. Unless the hands are the site being treated, wash your hands after rubbing in the gel, to avoid accidental contact with the mouth and eyes.

Voltaren Emulgel 12 Hours is for external use only.

How long to use Voltaren Emulgel 12 Hours?

Do not use **Voltaren Emulgel 12 Hours** for more than 14 days for soft-tissue injuries or soft tissue rheumatism. **Voltaren Emulgel 12 Hours** should not be applied over a prolonged period of time on large areas of skin, unless under a medical prescription. Longer treatment may be recommended by a doctor.

4. Possible side effects:

The use of Voltaren Emulgel 12 Hours can cause the following side effects: in rare to very rare cases, the side effects can be serious.

Stop applying **Voltaren Emulgel 12 Hours** and see your doctor immediately in case of:

- Skin rash with blistering, hives
- Wheezing, shortness of breath, or tightness in the chest (asthma)
- Swelling of the face, lips, tongue or throat.
- The following side effects are usually mild and passing:
- Common: skin rash, itching, redness, burning sensation of the skin.
- In very rare cases, the skin may be more sensitive to the sun. Symptoms of this increased sensitivity of the skin are sunburn with itching, swelling and blistering.

If you notice any side effects that are not mentioned in this leaflet, please tell your doctor or pharmacist.

5. How to store Voltaren Emulgel 12 Hours

- Store below 30°C.

Keep this medicine out of the reach of children.

- Do not use Voltaren Emulgel 12 Hours after the expiry date which is stated on the carton and tube after EXP.

Warnings and precautions:

- Voltaren Emulgel 12 Hours should not be applied on open wounds (e.g. abrasions, cuts) or on damaged skin (e.g. eczema, skin rash).
- Stop the treatment immediately if a skin rash develops after applying the product.
- 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 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 12 Hours, some patients may develop mild, localized skin irritation.
- Inform your doctor, pharmacist or 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).
- Avoid contact with the eyes and mucous membranes. If you do get the product in your eyes, flush them thoroughly with running water. Inform your doctor if you have persistent disorders.

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

Taking other medicines with Voltaren Emulgel 12 Hours

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including those obtained without a medical prescription.

Pregnancy and breastfeeding

During the 1st and 2nd trimester of pregnancy and during breast-feeding, Voltaren Emulgel 12 Hours should not be used, except with a doctor's formal prescription. During the last 3 months of pregnancy, Voltaren Emulgel 12 Hours must not be used as it could harm your unborn child or cause problems at delivery.

If you are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

In case of compelling indication, Voltaren Emulgel 12 Hours should not be applied on the chest or large areas of the skin and not over a prolonged period.

Effects of other ingredients (excipients):

Voltaren Emulgel 12 Hours contains:

- Propylene glycol, which may cause mild localized skin irritation in some people.
- Butylhydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

6. What is in the pack and further information

What Voltaren Emulgel 12 Hours contains:

The active substance is diclofenac diethylamine. Each gram of gel contains 23.2 mg of diclofenac diethylamine. 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.

What Voltaren Emulgel 12 Hours looks like and contents of the pack:

Voltaren Emulgel 12 Hours is a white to practically white, cooling, non-greasy, non-staining cream-like gel. The product comes in packs of 50, 100 and 150 g not all pack sizes may be marketed.

Manufacturer

GSK Consumer Healthcare SARL, Nyon, Switzerland
MAH: GSK Consumer Healthcare Schweiz AG, Switzerland.
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(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