

Voltaren[®]

12 Emulgel 12 Hours

Diclofenac diethylamine



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

Always use Voltaren 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 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.

Where to find information in this leaflet

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

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

Voltaren 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. The active substance targets deep inflamed tissues.

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

Voltaren 12 Hours can be used to treat:

- Muscle and joints injuries (e.g. sprains, strains, bruises, backache, sports injuries), relieving pain quickly, including moderate to strong pain, improving patient mobility and helping recovery to normal function;
- Tendonitis (e.g. tennis elbow), swelling around elbow or knee;
- Mild arthritis of the knee or fingers.

Voltaren 12 Hours is intended for use in adults and children aged 12 years and older.

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

Do not use Voltaren 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); skin rash with blisters or hives; swelling of the face or tongue; runny nose.

- You are in the last 3 months of pregnancy.

If any of these apply to you, do not use Voltaren 12 Hours

If the pain and swelling do not improve within 7 days, or if they get worse, tell your doctor.

If you use more Voltaren 12 Hours than you should

- 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, contact your doctor immediately.

If you forget to use Voltaren 12 Hours

If you miss your application of Voltaren 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 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 12 Hours to use for adults and adolescents over 12 years of age?

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

How to apply Voltaren 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 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. 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 12 Hours is for external use only.

How long to use Voltaren 12 Hours

Do not use Voltaren 12 Hours for more than:

- 2 weeks for muscle and joints injuries (e.g. sprains, strains, bruises) or tendonitis
 - 3 weeks for arthritis pain
- Longer treatment may be recommended by a doctor.

4. Possible side effects

Like all medicines, Voltaren 12 Hours 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 allergy, STOP using Voltaren 12 Hours and tell a doctor or pharmacist immediately:

- Skin rash with blisters; hives (may affect between 1 and 10 in every 10,000 people).
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma) (may affect less than 1 in every 10,000 people).
- Swelling of the face, lips, tongue or throat (may affect less than 1 in every 10,000 people).

Other side effects which may occur are usually mild, passing and harmless (if you are concerned, tell a doctor or pharmacist).

Common side effects (may affect between 1 and 10 in every 100 people)

- Skin rash, itching, reddening or smarting of the skin
- Very rare side effects** (may affect less than 1 in every 10,000 people)

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

If you get any side effects which worry you (even side effects not listed in this leaflet), talk to your doctor or pharmacist.

5. How to store Voltaren 12 Hours

- Store below 30 °C.

Keep this medicine out of the reach of children.

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

Warnings and precautions:

- Do NOT apply to skin with conditions such as cuts, open wounds, or on skin that has a rash or eczema.
- Voltaren 12 Hours is for external use only. Do not use it in the mouth. Do not swallow it. Wash your hands after use. Be careful not to get Voltaren 12 Hours 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 the gel under airtight (plastic) bandages.

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

Children (under 12 years of age)

Do NOT use Voltaren 12 Hours on a child under 12 years of age.

Taking other medicines with Voltaren 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 breast-feeding

Do not use Voltaren 12 Hours 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 12 Hours if you are breast-feeding.

If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking any medicine.

Effects of other ingredients (excipients):

Voltaren 12 Hours contains:

- Propylene glycol, which may cause mild localised 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 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 12 Hours looks like and contents of the pack

Voltaren 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

Novartis Consumer Health SA, Nyon, Switzerland

This leaflet was last approved on:

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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