

## PATIENT INFORMATION LEAFLET (PIL)

# Voltaren<sup>®</sup>

## Emulgel<sup>®</sup> 1.16% gel



Voltaren Emulgel 1.16% gel (each 1g contains 11.6mg of diclofenac diethylamine).

### For External Use only.

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects listed or not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse.

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### 1. What is contained in Voltaren Emulgel 1.16% gel?

1g Voltaren Emulgel contains 11.6 mg diclofenac diethylamine (active ingredient) which corresponds to 10 mg of diclofenac sodium.  
Excipients: Carbomer (Carbopol 974P), macrogol cetostearyl ether (Cetomacrogol 1000), cocoyl caprylocaprate (Cetiol LC), diethylamine, propylene glycol (1,2 propylene glycol, dist.), isopropyl alcohol, mineral oil (liquid paraffin, heavy), perfume cream 45 (containing benzyl benzoate), purified water.

### 2. What is Voltaren Emulgel 1.16% and what is it used for?

Voltaren Emulgel contains the active ingredient diclofenac, which belongs to a group of medicines called Non-steroidal anti-inflammatory drugs (NSAIDs)

Voltaren Emulgel has analgesic and anti-inflammatory properties and, due to the aqueous-alcoholic base, has a soothing and cooling effect. Voltaren Emulgel is used for the external treatment of pain, inflammation and swelling in:

- Injuries of the tendons, ligaments, muscles and joints, e.g. sprains, bruises, strains or back pain after sports or accidents
- Localized forms of soft tissue rheumatism such as tendonitis (tennis elbow), shoulder-hand syndrome, bursitis, periarthropathy.
- The symptomatic treatment of osteoarthritis of small and medium-sized joints located close to the skin such as the finger joints or knee joints.

### 3. What you need to know before using Voltaren Emulgel 1.16%?

#### a. Do Not Use Voltaren Emulgel 1.16% in cases of:

- Hypersensitivity to diclofenac sodium or to any of the excipients contained in the medicine.

- Patients who have attacks of asthma, urticaria, or acute rhinitis precipitated by acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
- Pregnancy during the last trimester.

#### b. Warnings and precautions

- Do not apply Voltaren Emulgel 1.16% on open wounds (e.g. abrasions, cuts) or on damaged skin (e.g. eczema, skin rash). Discontinue the treatment if a skin rash develops after applying the product.
- Avoid applying on large areas of skin or for a longer than approved duration of use, except on medical prescription. The possibility of systemic adverse events from application of Voltaren cannot be excluded if the preparation is used on large areas of skin and over a prolonged period.
- Voltaren Emulgel 1.16% 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 Emulgel 1.16% in your eyes. In case of contact, rinse your eyes well with water. See your doctor if any discomfort persists.
- Do not swallow the product. If you accidentally swallow the Emulgel or if a child does, contact your doctor immediately.
- A brace or wrap commonly used for injuries like sprains can be used but do not use under airtight (plastic) bandages.
- Do not use Voltaren Emulgel 1.16% on a child under 12 years of age.
- Voltaren Emulgel 1.16% contains propylene glycol and benzyl benzoate, which may cause mild, localized skin irritation in some patients.

#### Interaction with other medicinal products and other forms of interaction

Since systemic absorption of diclofenac from topical application is very low, such interactions are very unlikely.

#### Special Warning:

##### Cardio Vascular Risk:

- NSAIDs may cause an increased risk of cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. Diclofenac is contraindicated for treatment of peri operative pain in the setting coronary artery bypass graft (CABG) surgery.

##### Gastrointestinal Risk:

- NSAIDs cause an increased risk of serious gastrointestinal adverse events including inflammation, bleeding, ulceration, and perforation of stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients at greater risk for serious gastrointestinal events.

#### c. Pregnancy, breast-feeding, and fertility

##### Pregnancy

The use of diclofenac in pregnant women has not been studied; therefore, Voltaren Emulgel 1.16% should not be used during pregnancy.

Voltaren Emulgel is contraindicated during the third trimester of pregnancy, owing to the possibility of uterine inertia, fetal renal impairment with subsequent oligohydramnios and/or premature or postnatal development.

Animal studies have shown no evidence of direct or indirect harmful effects on pregnancy, embryonal/fetal development, childbirth or postnatal development.

#### Breast-feeding

It is not known whether topical diclofenac is excreted in breast milk; therefore, Voltaren Emulgel 1.16% is not recommended during breast-feeding. If there are compelling reasons for using it, it should not be applied to the breasts or to large areas of skin, nor should it be used for a prolonged period.

#### Fertility

There are no data available on the use of topical formulations of diclofenac and its effects on fertility in humans.

#### **d. Driving and using machines**

Cutaneous Application of Voltaren Emulgel 1.16% has no influence on the ability to drive and use machines.

#### **4. How to use Voltaren Emulgel 1.16%?**

##### Adults and adolescents aged 12 and over

Depending on the size of the painful or swollen area or surfaces to be treated, rub, with light massage, or with more pronounced massage in case of muscular pain, an amount of 2-4 g of Voltaren Emulgel (cherry to walnut sized amount Sufficient to treat an area of about 400-800cm<sup>2</sup>) 3 to 4 times a day. Wash hands after application, except for the treatment of finger arthritis. When used without medical prescription, patients should consult their doctor if the condition does not improve within 7 days, or if it gets worse.

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.

##### Children under 12 years

It is not recommended for use in children below 12 years

##### Elderly patients (over 65 years of age)

The usual adult dosage of Voltaren

#### **How long to use Voltaren Emulgel 1.16%?**

The duration of treatment depends on the indication and clinical response. Do not use Voltaren Emulgel 1.16% 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.

When used without medical prescription, patients should consult their doctor if the condition does not improve within 7 days, or if it gets worse.

If you miss your application of Voltaren Emulgel 1.16% 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.

#### **Overdose**

The low systemic absorption of topical diclofenac makes overdose very unlikely.

However undesirable effects, similar to those observed following an overdose of Voltaren tablets, can be expected if Voltaren Emulgel 1.16% is inadvertently ingested (1 unit of 100g contains the equivalent of 1g diclofenac sodium).

In the event of accidental ingestion, resulting in significant systemic adverse effects, general therapeutic measures normally adopted to treat poisoning with non-steroidal anti-inflammatory medicines should be

used. Gastric decontamination and the use of activated charcoal should be considered, especially within a short time of ingestion.

#### **5. Possible side effects**

Like all medicines, the use of Voltaren Emulgel can cause the following side effects, although not everybody gets them.

<u>Infections and infestations</u> Very rare: Rash pustular
<u>Immune system disorders</u> Very rare: Hypersensitivity (including urticaria), angiodema
<u>Respiratory, thoracic and mediastinal disorders</u> Very rare: Asthma
<u>Skin and subcutaneous tissue disorders</u> Common: Dermatitis (including contact dermatitis), rash, erythema, eczema, pruritus Rare: Dermatitis bullous Very rare: Photosensitivity reaction

If any of the above side effects or any other side effects that are not described in this leaflet occur, you should stop immediately the treatment with Voltaren Emulgel and inform your doctor or your pharmacist.

#### **6. How to store Voltaren Emulgel 1.16%?**

Store below 30°C.

This medicine must not be used beyond the date indicated after expiry date «EXP» on the container.

Protect from sunlight. Do not open by force or burn, even after use.

Medicines should be kept out of the reach and sight of children.



#### **Manufactured by**

Novartis Consumer Health SA  
Nyon, Switzerland

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#### **To report any side effect(s):**

The National Pharmacovigilance and Drug Safety Centre (NPC)

Fax: +966-11-205-7662

Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340

Toll free phone: 8002490000

E-mail: npc.drug@sfd.gov.sa

Website: www.sfd.gov.sa/npc

#### **THIS IS A MEDICAMENT**

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

#### **Keep medicament out of reach and sight of children.**

Council of Arab Health Ministers  
Union of Arab Pharmacists