

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

20 g, 50 g - S0

100 g, 50 ml, 75 ml or 100 ml - S1

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Voltaren® Emulgel® (1,16 g diclofenac diethylamine corresponding to 1 g diclofenac sodium per 100 g gel).

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

Voltaren Emulgel is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Voltaren Emulgel carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Voltaren Emulgel with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

### 1. WHAT VOLTAREN EMULGEL CONTAINS

The active substance is diclofenac diethylamine 1,16 g corresponding to 1 g diclofenac sodium per 100 g.

The base is a fatty emulsion containing isopropanol and propylene glycol, in an aqueous gel.

The other ingredients are carbomer 974 P, cocoyl caprylocaprate, purified water, diethylamine, liquid paraffin, macrogol cetostearyl ether, perfume cream 45.

### 2. WHAT VOLTAREN EMULGEL IS USED FOR

Voltaren Emulgel is specially formulated for rubbing into the skin. The active substance, diclofenac, is one of the group of medicines called non-steroidal anti-inflammatory drugs.

**Voltaren Emulgel is used to relieve pain and reduce inflammation and swelling in a number of painful conditions affecting the joints and muscles. It can be used to treat:**

- muscle and joints injuries (e.g. sprains, strains, bruises, backache, sports injuries)
- tendonitis (e.g. tennis elbow)
- mild arthritis of the knee or fingers.

### 3. BEFORE YOU USE VOLTAREN EMULGEL

#### **Do not use Voltaren Emulgel:**

- If you ever had an allergic reaction to diclofenac or other non-steroidal anti-inflammatory medicines used to treat pain, fever or inflammation, such as ibuprofen or aspirin (a substance also used to prevent blood clotting) or any other ingredients contained in this medicine. If you are not sure, ask your doctor or pharmacist.

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 allergic to any of the ingredients in Voltaren Emulgel (these are listed at the end of the leaflet, section 1)
- Voltaren should not be used by patients with porphyria.

If any of these applies to you, do not use Voltaren Emulgel.

#### **Take special care with Voltaren Emulgel:**

- Do not apply Voltaren Emulgel to skin with conditions such as cuts, open wounds or on skin that has a rash or eczema.
- Be careful not to get Voltaren Emulgel in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.
- Voltaren Emulgel is for external use only. Do not use it in the mouth. Do not swallow it.

#### **Pregnancy and Breastfeeding:**

Do not use Voltaren Emulgel if you are in the last 3 months of pregnancy or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

#### **Important information about some of the ingredients of Voltaren Emulgel:**

The gel formulation contains propylene glycol, which may cause a mild localised skin irritation in certain people.

**Using other medicines with Voltaren Emulgel:**

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

**4. HOW TO USE VOLTAREN EMULGEL**

Do not share medicines prescribed for you with any other person.

For adults and adolescents over 12 years of age.

Apply Voltaren Emulgel 3 to 4 times a day on the painful area.

**How to apply Voltaren Emulgel:**

- 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.
- Gently rub a small amount of Voltaren Emulgel into the skin where you have pain or swelling. The amount needed will vary depending upon the size of the painful or swollen area. Usually, an amount ranging in size from a cherry to a walnut will be sufficient. You may notice a slight cooling effect when you rub the gel.
- Wash your hands after rubbing in Voltaren Emulgel, unless of course they are the site being treated.

**How long should you use Voltaren Emulgel:**

- Do not use Voltaren Emulgel for more than 2 weeks for muscle and joints injuries (e.g. sprains, strains, bruises) or tendonitis, or 3 weeks for arthritis pain, unless longer treatment is recommended by a doctor.
- If the pain and swelling do not improve within 7 days, or if they get worse, tell your doctor.

**If you use more Voltaren Emulgel than you should:**

In the event of overdosage, wipe off the surplus gel with a tissue and consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to use Voltaren Emulgel:**

If you miss applying Voltaren Emulgel at the correct time, apply it as soon as possible and then carry on as normal. Do not apply a double quantity.

**If you accidentally swallow Voltaren Emulgel:**

Seek medical advice immediately in case of accidental swallowing.

**5. POSSIBLE SIDE EFFECTS**

Voltaren Emulgel can have side effects.

Some rare and very rare side effects might be serious.

*If you experience any of the following signs of allergy, STOP using Voltaren Emulgel and tell a doctor or pharmacist immediately:*

- Skin rash with or without blisters; hives. These are likely to affect 1 to 10 people out of 10,000.
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma). These are likely to affect less than 1 person out of 10,000.
- Swelling of the face, lips, tongue or throat. These are likely to affect less than 1 person out of 10,000.

*Less serious side effects*

Other side effects which may occur are usually mild, passing and harmless. If you are concerned, tell a doctor or pharmacist as soon as you can.

- Skin rash, itching, reddening or smarting of the skin are common after use. These side effects are likely to affect 1 to 10 people out of 100.
- In very rare cases, the skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering. This is likely to affect less than 1 person out of 10,000.

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**6. STORING AND DISPOSING OF VOLTAREN EMULGEL**

- Keep Voltaren Emulgel out of the reach and sight of children.
- Store at or below 25 °C. Protect the pressurized containers from direct sunlight and do not pierce or burn even when empty.
- Do not use after the expiry date shown on the carton and tube or pump dispenser.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **7. PRESENTATION OF VOLTAREN EMULGEL**

20 g, 50 g and 100 g Aluminium laminated tubes with white or blue polypropylene caps.

Pressurised aluminium 50 ml, 75 ml or 100 ml containers containing a multilayer pouch (low density polyethylene layer in contact with the product) with a high-density polyethylene/titanium oxide valve and polyoxymethylene actuator with protective cap.

## **8. IDENTIFICATION OF VOLTAREN EMULGEL**

Voltaren Emulgel is a white, cooling, non-greasy, non-staining cream-like gel.

## **9. REGISTRATION NUMBER**

U/3.1/77

## **10. NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER**

GlaxoSmithKline Consumer Healthcare SA (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1

Cape Town, 7460

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## **11. DATE OF PUBLICATION**

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® Registered Trade Mark

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