

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Voltarol 12 hour Emulgel 2.32% Gel**

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

Always use Voltarol 12 Hour Emulgel 2.32% Gel exactly as described in this leaflet. 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 Voltarol 12 Hour Emulgel 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.

#### **In this leaflet**

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#### **1. What Voltarol 12 Hour Emulgel is and what it is used for**

Voltarol 12 Hour Emulgel 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. Voltarol 12 Hour Emulgel is used to relieve pain and reduce inflammation and swelling in a number of painful conditions affecting the joints and muscles. Voltarol 12 Hour Emulgel can be used to treat:

- muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries), relieving pain and helping recovery back to normal function;
- tendonitis (e.g. tennis elbow), swelling around elbow or knee;

Voltarol 12 Hour Emulgel is intended for use in adults and children aged over 14 years.

## **2 What you need to know about Voltarol 12 Hour Emulgel**

### **Do not use Voltarol 12 Hour Emulgel if you:**

- are allergic (hypersensitive) to diclofenac or other medicines used to treat pain, fever or inflammation, such as ibuprofen or aspirin (a substance also used to prevent blood clotting), or any of the other ingredients of this medicine (see Section 6 and end of Section 2). 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.
- are using any other medicine containing diclofenac or are taking oral NSAIDs such as aspirin or ibuprofen.
- have severe joint pain of recent onset that is not related to an injury or period of overuse.
- feel ill, have a temperature or any other symptoms that accompany the pain.
- are in the last 3 months of pregnancy.

**If any of these apply to you, do not use Voltarol 12 Hour Emulgel.**

### **Take special care with Voltarol 12 hour Emulgel**

- Do not apply the gel to skin that has (i) a rash or eczema (ii) cuts or open wounds. Stop the treatment if a skin rash develops after applying the product. Avoid applying on large areas of skin and over a prolonged period of time, unless under medical advice.
- Voltarol 12 Hour Emulgel is for external use only. Do not use it in the mouth. Do not swallow it. Wash your hands after use unless they are the area to be treated. Be careful not to get Voltarol 12 Hour Emulgel 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 or have ever had asthma speak to your doctor or pharmacist before using the gel.
- If you have a stomach or duodenal ulcer (or a history of), tell your doctor or pharmacist before using the gel.

**If you have any questions, talk to your doctor or pharmacist before using Voltarol 12 Hour Emulgel**

**This medicine is not recommended for use in children under 14 years of age.**

### **Taking other medicines with Voltarol 12 Hour Emulgel**

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

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Voltarol 12 Hour Emulgel must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. Voltarol 12 Hour Emulgel should only be used under medical advice during the first 6 months of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

Voltarol 12 Hour Emulgel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Voltarol 12 hour Emulgel should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period of time.

Consult your doctor or pharmacist for further information if you are pregnant or breastfeeding.

### **Effects of other ingredients (excipients)**

Voltarol 12 Hour Emulgel contains:

- **propylene glycol**, which may cause a 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.

### **3. How to use Voltarol 12 Hour Emulgel**

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

#### **How much Voltarol 12 Hour Emulgel to use**

##### **For adults and adolescents 14 years and over.**

Apply the gel 2 times a day (preferably morning and evening) on the painful area.

#### **How to apply Voltarol 12 Hour Emulgel**

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 1 penny to a 2 pence piece will usually be sufficient (2–4g). You may notice a slight cooling effect when you rub the gel in. Only use the smallest amount of Voltarol 12 Hour Emulgel needed to relieve your pain but never use more than 8g per day and 56g in one week.
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 (see Section 2).

Voltarol 12 Hour Emulgel is for external use only.

#### **How long to use Voltarol 12 Hour Emulgel for**

**Do not** use Voltarol 12 Hour Emulgel for more than 7 days 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.

In children aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

#### **If you use more Voltarol 12 Hour Emulgel 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 Voltarol 12 Hour Emulgel**

If you miss your application of Voltarol 12 Hour Emulgel 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.

#### **4. Possible side effects**

Like all medicines, Voltarol 12 Hour Emulgel 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 Voltarol 12 Hour Emulgel and tell a doctor or pharmacist immediately:

- Skin rash with blisters; hives. (These side effects are likely to affect 1 to 10 people in every 10,000).
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma). (These side effects are likely to affect less than 1 person in every 10,000).
- Swelling of the face, lips, tongue or throat. (These side effects are likely to affect less than 1 person in every 10,000).

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

##### **Common side effects**

(likely to affect between 1 and 10 in every 100 patients)

- Skin rash, itching, reddening or smarting of the skin

##### **Very rare side effects**

(likely to affect less than 1 in every 10,000 patients)

- 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.**

##### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Voltarol 12 Hour Emulgel**

- Keep this medicine out of the reach and sight of children.
- Do not use Voltarol 12 Hour Emulgel after the expiry date which is stated on the carton and tube after EXP.
- Do not store above 30°C.
- Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### **6. What is in the pack and further information**

##### **What Voltarol 12 Hour Emulgel contains**

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

The other ingredients (excipients) are butylhydroxytoluene, carbomers, cocoyl caprylocaprates, diethylamine, isopropyl alcohol, liquid paraffin, macrogol cetostearyl ether, oleyl alcohol, propylene glycol,

perfume and purified water (see end of Section 2 for further information). **What Voltarol 12 Hour Emulgel looks like and contents of the pack**

Voltarol 12 Hour Emulgel is a white to practically white, cooling, non-greasy, non-staining cream-like gel.

The product comes in packs of 30g and 50g. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited,

Brentford,

TW8 9GS,

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