

Patient Information Leaflet

Voltarol[®] Pain-eze



Emulgel[®] (diclofenac diethylammonium)

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

This medicine is available without prescription. However, you still need to use Voltarol Pain-eze Emulgel carefully to get the best results from it.

- 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 symptoms worsen or do not improve within 7 days.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What Voltarol Pain-eze Emulgel is and what it is used for
2. Before you use Voltarol Pain-eze Emulgel
3. How to use Voltarol Pain-eze Emulgel
4. Possible side effects
5. How to store Voltarol Pain-eze Emulgel
6. Further information

1. What Voltarol Pain-eze Emulgel is and what it is used for

Voltarol Pain-eze 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 and is used to relieve pain and reduce inflammation and swelling in painful conditions affecting the joints and muscles. Voltarol Pain-eze Emulgel can be used to treat:

- muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries)
 - tendonitis (e.g. tennis elbow)
- #### 2. Before you use Voltarol Pain-eze Emulgel
- DO NOT use Voltarol Pain-eze Emulgel if you:**
- have an allergy (hypersensitivity) to any of the ingredients in the product (see Section 6 'What Voltarol Pain-eze Emulgel contains').
 - have ever had an allergic reaction to diclofenac or other medicines used to treat pain, fever or inflammation, such as aspirin (acetylsalicylic acid) or ibuprofen. 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 in the last 3 months of your pregnancy (see also pregnancy and lactation section).
 - are using any other medicine containing diclofenac or are taking oral NSAIDs such as aspirin or ibuprofen.

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

Take special care with Voltarol Pain-eze 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.

- Be careful when sunbathing or using sun lamps as your skin may be more sensitive to sunlight.
- If you have a stomach or duodenal ulcer (or a history of), tell your doctor or pharmacist before using the gel.
- If you have or have ever had asthma speak to your doctor or pharmacist before using the gel.

Taking other medicines

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

Do not use Voltarol Pain-eze Emulgel if you are already taking diclofenac tablets or other NSAID pain/inflammation tablets (e.g. aspirin or ibuprofen).

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 taking this medicine.

Voltarol Pain-eze 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 Pain-eze 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 Pain-eze Emulgel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Voltarol Pain-eze 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.

Driving and using machines

Voltarol Pain-eze Emulgel, when used as directed, is not expected to have any effect on your ability to drive or use machines.

Important information about some of the ingredients of Voltarol Pain-eze Emulgel

The gel formulation contains propylene glycol and benzyl benzoate, which may cause mild localised skin irritation in some people.

3. How to use Voltarol Pain-eze Emulgel

- 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.
- The gel is for external use only. Do not use it in your mouth. Inform your doctor immediately in case of accidental swallowing.
- Do not put Voltarol Pain-eze Emulgel in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.

Adults and adolescents 14 years and over

1. Take the tube out of the carton:
 - a. For the aluminium tube: Before first use, pierce the

10

Pharma code 252

86 mm

sealing membrane of the tube with the spiked top of the cap. Do not use if seal is broken

- b. For the laminated tube: Unscrew and remove cap. When using for the first time, reverse the cap, engage with the nozzle, twist and remove the seal from the tube. Do not use if seal is broken.
2. Gently squeeze out a small amount of gel from the tube and apply to the painful or swollen area 3 to 4 times a day, slowly rubbing into the skin. The amount needed will vary depending on 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. You may notice a slight cooling effect when you rub the gel in.
3. In addition to applying the gel, the guidelines (known as "RICE") may be useful to help healing of sprains. See the end of this leaflet.
4. Do not rub the gel into cuts, open wounds or any other area where the skin is abnormal. After rubbing the gel into the skin, do not cover with bandages or sticking plaster.
5. Be careful not to get the gel in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.
6. Wash your hands after rubbing in Voltarol Pain-eze Emulgel, unless your hands are the site being treated. Replace the cap.
7. Apply at least four hours between applications of the gel. Do not apply more than 4 times in any 24 hour period.

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

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.

Do not use Voltarol Pain-eze 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 worsen, speak to your doctor. If symptoms do not improve within this time, or they get worse, consult your doctor.

If you use more Voltarol Pain-eze Emulgel than you should If you or a child accidentally swallows Voltarol Pain-eze Emulgel, contact your doctor or accident and emergency department immediately.

If you forget to use Voltarol Pain-eze Emulgel

If you miss your application of Voltarol Pain-eze Emulgel at the correct time, apply it as soon as you remember then carry on as normal. Do not apply a double quantity to make up for a forgotten application.

If you have any further questions on the use of this product, ask your pharmacist.

4. Possible side effects

Like all medicines, Voltarol Pain-eze 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 Pain-eze Emulgel 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.

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.

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

5. How to store Voltarol Pain-eze Emulgel

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Voltarol Pain-eze Emulgel after the expiry date stated on the carton and tube.

Medicines should not be disposed of 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. Further information

What Voltarol Pain-eze Emulgel contains

The **active substance** is diclofenac diethylammonium (1.16%) equivalent to 1g of diclofenac sodium in each 100 g of gel.

The **other ingredients** are carbomers, macrogol cetostearyl ether, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, propylene glycol, liquid paraffin, perfume (contains benzyl benzoate), purified water (*see end of Section 2 'Important information about some of the ingredients of Voltarol Pain-eze Emulgel' for propylene glycol*).

What Voltarol Pain-eze Emulgel looks like and contents of the pack

Voltarol Pain-eze Emulgel is a white, cooling, non-greasy, non-staining cream-like gel, packed inside an aluminium or aluminium laminated tube with plastic screw cap. This is supplied in a carton and comes in packs of 10, 30, 50 g, and 100g (not all pack sizes may be marketed).

Marketing authorisation holder

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

Manufacturer

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

RICE advice:

In addition to applying the gel, these guidelines (known as "RICE") may be useful to help healing of sprains.

Day 1 to Day 3

REST	Stop using the injured joint as much as possible in the first 48 hours. If you are unable to use the joint, e.g. put any weight at all on an ankle, it may be broken, so see a doctor as soon as possible so that an X-ray can be done
ICE	To decrease both swelling and pain, take a bag of ice (or frozen vegetables), wrap it in a towel, and apply for 10-20 minutes (longer may cause frostbite). Do this every hour, or at least 3 times a day.
COMPRESSION	Lightly wrap your joint/the affected area with an elastic bandage, make sure it is not so tight that it cuts off circulation to you limb.
ELEVATION	If possible raise the affected limb as much as possible in the first 48 hours to reduce swelling and pain

This leaflet was last revised in February 2016

GB 936645 - 21186797



12

10