

Voltarol® Pain-eze Emulgel®

Diclofenac diethylammonium



WHAT YOU NEED TO KNOW ABOUT VOLTAROL PAIN-EZE EMULGEL

Please read this leaflet carefully before you start to use this gel. If you have any questions, want more information, or you are not sure about anything, please ask your doctor or pharmacist.

WHAT'S IN VOLTAROL PAIN-EZE EMULGEL?

The gel contains 1.16% of diclofenac diethylammonium, which is equivalent to 1 g of diclofenac sodium in each 100 g of gel. Diclofenac, the active ingredient in the gel, is one of a group of medicines called non-steroidal anti-inflammatory analgesics (NSAIDs) which reduce pain and inflammation.

The gel contains the following inactive ingredients: diethylamine, carbomer, macrogol cetostearyl ether, cocoyl caprylocaprate, isopropylalcohol, liquid paraffin, perfume, propylene glycol, purified water. Voltarol Pain-eze Emulgel comes in a tube of 50 g. Each 50 g tube contains the equivalent of 0.5 g diclofenac sodium in a white, non-greasy, nonstaining gel.

Product Licence holder:

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Released onto the market by the Licence holder

WHAT IS VOLTAROL PAIN-EZE EMULGEL USED FOR?

This is a gel for application to the skin, used to relieve pain and reduce inflammation and swelling in a number of painful local conditions affecting the joints, muscles, tendons and ligaments:

- sprains, strains and soft tissue injuries
- muscular aches and pains

BEFORE USING VOLTAROL PAIN-EZE EMULGEL ASK YOURSELF THE FOLLOWING QUESTIONS

- Have you ever had an asthma attack, wheezing, urticaria (hives), or a runny nose after taking aspirin or other NSAID pain/anti-inflammatory medicine?
- Are you allergic to diclofenac or any of the ingredients in the gel (see "What's in Voltarol Pain-eze Emulgel?").
- Are you allergic to aspirin or any other NSAID?
- Are you pregnant or breast-feeding? If the answer to any of these questions is YES, do not use the gel.
- Do you have or have you ever had a stomach or duodenal ulcer?
- Are you taking any other prescribed medicines? If the answer to any of these questions is YES, tell your doctor or pharmacist before using this product.

OTHER SPECIAL WARNINGS

- Do not use if you are taking diclofenac tablets or other NSAID pain/inflammation tablets.
- This gel should not be used on children under 12 years of age.
- Your skin may be more sensitive to sunlight. Be careful when sunbathing or using sun lamps.
- If the gel is swallowed, tell your doctor at once or contact your nearest hospital casualty department.

USING VOLTAROL PAIN-EZE EMULGEL

It is important to use this product correctly. Follow the instructions carefully.

- Remove the seal from the end of the tube, see carton for details. Do not use if the seal is broken. Adults and children aged 12 and over.
- Gently rub a small amount of gel into the skin around the painful or swollen area. The amount of gel needed will vary depending upon the size of the painful or swollen area. Usually, a quantity the size of a 1 penny or 2 pence piece will be sufficient.

- You can apply the gel 3 to 4 times a day unless your doctor or pharmacist tells you otherwise. You may notice a slight cooling effect when you rub the gel into the skin.
- 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, in order to limit further injury. If you are unable to use the joint, eg 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 – This is an effective way 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). This can be done as often as every hour, but do it at least 3 times a day.

COMPRESSION – Lightly wrap your joint/the affected area with an elastic bandage, but not so tight that it cuts off circulation to your limb.

ELEVATION – Raising the affected limb is a very effective way to limit swelling and pain. Raise the injured part as much as possible in the first 48 hours.

- Allow at least four hours between applications of the gel. Do not apply more than 4 times in any 24 hour period.

- 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.

- Be careful not to get the gel in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.
- Wash your hands after rubbing in the gel (*unless they are the site being treated*).
- Do not use the gel for more than 7 days, unless longer treatment is recommended by a doctor. If symptoms do not improve within this time, or they get worse, consult your doctor.
- If you miss applying the product at the correct time, rub it in when you remember and then next apply the gel at the usual time.

Do not apply a double dose.

AFTER USING VOLTAROL PAIN-EZE EMULGEL

It is unusual for this product to cause problems. Occasionally the following unwanted effects can occur:

- Itching, reddening, smarting or blistering of the skin, where the gel has been applied. These effects are often mild and may wear off after a few days' treatment. If they are severe or last for more than a few days, tell your doctor.

Very rarely, other effects may occur and your doctor should be informed immediately:

- Increased sensitivity of skin to sunlight. Some people may experience the following symptoms when using Voltarol Pain-Eze Emulgel:
 - Skin rash covering all your body.
 - Wheezing or asthma attack, angio-oedema (swelling of the face and mouth or tongue).
 - Stomach ache or heartburn.

If you are affected in this way, discontinue use and tell your doctor immediately.

If this gel upsets you in any other way, tell your doctor or pharmacist.

STORING YOUR MEDICINE

- Do not store above 30°C.
- Keep all medicines out of reach and sight of children.
- The expiry date for this medicine is given on the carton and tube. Do not use after this date.

The information in this leaflet applies only to Voltarol Pain-eze Emulgel. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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