# Voltaren Emulgel

Back & Muscle Pain

(No Mess Applicator*)

*Diclofenac diethylamine gel 11.6 mg/g (1.16% w/w)*

This leaflet is part III of a three-part "Product Monograph" published when **Voltaren Emulgel** Back & Muscle Pain was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about **Voltaren Emulgel** Back & Muscle Pain.

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

- Keep this leaflet. You may need to read it again.
- Contact your doctor or pharmacist if you have any questions about the drug or need more information or advice.

## ABOUT THIS MEDICATION

**What the medication is used for:**

**Voltaren Emulgel** Back & Muscle Pain

- For the relief of aches and pain associated with acute, localized minor muscle or joint injuries such as sprains, strains or sports injuries (*e.g.* sprain of ankle, strain of shoulder or back muscles). Rest may also be helpful to assist the relief of associated discomfort.

**What it does:**

**Voltaren Emulgel** Back & Muscle Pain is specially formulated for rubbing into the skin to relieve acute pain affecting the joints and muscles. The active substance, diclofenac, is one of the groups of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) that work within the body by blocking the production of particular substances, called prostaglandins, which are involved in the development of pain and inflammation.

**When it should not be used:**

- If you are currently taking diclofenac or any other over-the-counter or prescription oral non-steroidal anti-inflammatory drug (NSAID) which are used to treat pain, fever or inflammation, such as ibuprofen, acetylsalicylic acid (ASA) or naproxen. If you are not sure, ask your doctor or pharmacist.
- If in the past you have had allergic reactions to diclofenac or any other NSAIDs such as ibuprofen, ASA or naproxen.
- If you have attacks of asthma, urticaria (hives), or acute rhinitis (nasal inflammation, irritation or stuffy nose that lasts less than 6 weeks), swelling of the face or tongue, runny nose after taking ASA or other NSAIDs
- If you are allergic to any of the nonmedicinal ingredients in the gel (see list of nonmedicinal ingredients).
- If you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery.

If any of these applies to you, do not use this medicine. If you are not sure, ask your doctor or pharmacist.

**What the medicinal ingredient is:**

Diclofenac diethylamine

**What the nonmedicinal ingredients are:**

**Voltaren Emulgel** Back & Muscle Pain 1.16% w/w gel contains the following nonmedicinal ingredients: Carbomer, cocoyl caprylocaprate, diethylamine, fragrance (containing benzyl benzoate), isopropyl alcohol, liquid paraffin, macrogol cetostearyl ether, propylene glycol, purified water.

Propylene glycol and benzyl benzoate may cause mild localised skin irritation in some people.

**What dosage forms it comes in:**

**Voltaren Emulgel** Back & Muscle Pain 1.16% w/w gel comes in tubes of 20 g, 30 g, 50 g, 100 g, 120 g* and 150 g.

The gel is white, cooling, non-greasy, non-staining, cream-like.

## WARNINGS AND PRECAUTIONS

BEFORE you use **Voltaren Emulgel** Back & Muscle Pain talk to your doctor or pharmacist if:

- You have a history of stomach ulcers or take medication for such gastrointestinal disorders.
- You are pregnant, think you may be pregnant, are planning to have a baby or are breast feeding.
- You are taking, or have recently taken, any other medicines, including Over the Counter drugs.

**Voltaren Emulgel** Back & Muscle Pain is not intended for use in children under the age of 16.

Do not apply to cuts or open wounds or to skin that has a rash or eczema. 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, unless under medical advice.

A brace or wrap commonly used for injuries like sprains can be used but do not wrap the skin with an airtight (plastic) or occlusive dressing when using **Voltaren Emulgel** Back & Muscle Pain.

In very rare cases, your skin may be more sensitive to sunlight while using this product. Use caution during sun exposure or when using tanning booths/sun lamps. Possible signs are sunburn with itching, swelling and blistering.

Be careful not to get it in your eyes. If this happens, rinse your eyes well with clean water and tell a doctor or a pharmacist.

**Voltaren Emulgel** Back & Muscle Pain is for EXTERNAL USE ONLY.

Do not use it in the mouth, vaginal or anal areas.

Never swallow it.

Do not use right before or after heart surgery.

## INTERACTIONS WITH THIS MEDICATION

Check with your doctor or pharmacist if you are taking any other NSAIDs (e.g. ibuprofen, acetylsalicylic acid or naproxen) or anticoagulants (blood thinners), high blood pressure medication, oral anti-diabetic agents, fluoroquinolone antibiotics (*i.e.*, ofloxacin) or are taking medication for peptic ulcers, gastroesophageal disease or to control excess acidity. If you suspect a drug interaction, notify your doctor or pharmacist.

## PROPER USE OF THIS MEDICATION

**Usual dose:**

**Voltaren Emulgel** Back & Muscle Pain:

For adults and adolescents 16 years and older:

- Apply gel 3 to 4 times a day.
- The amount needed will vary depending upon the size of the painful or swollen area: 2 g to 4 g (1 g equals a strip approximately 2 cm long) gel will be sufficient to cover a 400 to 800 $cm^2$ area.
- Applicator: (See figure 1) To remove the seal before first use, remove the transparent protective cover and then unscrew the applicator. Use the star-shape groove located at the side of the applicator to remove the security seal of the tube. Screw the applicator back on the tube before dispensing the gel.
- Applicator: (See figure 1) To open, simply pull the white part of the applicator. Gently squeeze the tube to push the gel to the surface of the applicator. Use the applicator-capped tube as if it would be your fingers to gently and slowly rub the gel into the skin at the painful or swollen area. The slight pressure of rubbing in the gel will automatically close the applicator.
- You may notice a slight cooling effect when you rub the gel in.
- Applicator: (See figure 1) After use, clean the applicator with cotton towel or absorbent paper until visually dry and clean. Do not immerse or rinse under water. Do not use any solvent or detergent to clean the surface of the applicator. After cleaning, place the transparent protective cap back on the tube before storage. Do not reuse the applicator with another tube. Discard the tube with its applicator following the same procedure for disposal of any medication as recommended.
- Wash your hands after rubbing in **Voltaren Emulgel** Back & Muscle Pain to avoid accidental contact with the mouth and eyes, unless your hands are the site being treated.

The gel should not be used for more than 7 days for muscle and joint injuries unless recommended by a doctor. Talk to your doctor if your condition does not improve within 7 days, or if it gets worse.

Figure 1

Pull off the transparent protective cover

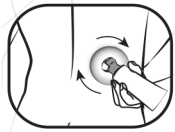
Unscrew the applicator cap

Use the key on the applicator cap to remove the star seal on the tube

Screw the applicator cap back on the tube

Pull white part to open

Squeeze the tube to release required amount of Emulgel



Apply to skin, closing cap on application

Clean the applicator with cotton towel or absorbent paper until visually dry and clean

**Overdose:**

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|---|
| In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms. |

If you use more gel than required you should wipe off the surplus gel with a tissue.

If you or a child accidentally swallows the gel, contact your doctor immediately.

**Missed Dose:**

If you miss applying **Voltaren Emulgel** Back & Muscle Pain at the correct time, apply it when you remember and then next apply it at the usual time. Do not apply a double quantity.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Itching, reddening or slight irritation of the skin are common after use of **Voltaren Emulgel** Back & Muscle Pain. These

symptoms are usually mild, passing and harmless. If you are concerned, tell a doctor or pharmacist. Discontinue the treatment if a skin rash develops after applying the product.

| SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM | | | |
|---|---|---|---|
| Symptom / effect | | Talk with your doctor or pharmacist | Stop taking drug and call your doctor or pharmacist |
| Some rare and very rare side effects might be serious | Skin rash with blisters; hives | ✓ | ✓ |
| | Wheezing, shortness of breath or feeling of tightness in the chest (asthma) | ✓ | ✓ |
| | Swelling of the face, lips, tongue or throat | ✓ | ✓ |
| Common | Skin rash, itching, reddening or smarting of the skin | ✓ | ✓ |
| Very rare side effects | The skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering | ✓ | ✓ |

This is not a complete list of side effects. For any unexpected effects while taking **Voltaren Emulgel** Back & Muscle Pain, contact your doctor or pharmacist.

## HOW TO STORE IT

**Voltaren Emulgel** Back & Muscle Pain should be stored between 15 °C and 30 °C.

**Voltaren Emulgel** Back & Muscle Pain should not be stored after the expiry date shown on the carton and tube.

Keep **Voltaren Emulgel** Back & Muscle Pain out of the reach and sight of children.

Do not use after the expiry date stated on the label.

## REPORTING SUSPECTED SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:

Online at MedEffect;
By calling 1-866-234-2345 (toll-free);
By completing a Consumer Side Effect Reporting Form and sending it by:

Fax to 1-866-678-6789 (toll-free), or
Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects.
The Canada Vigilance Program does not provide medical advice.

## MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be received by contacting the sponsor, GlaxoSmithKline Consumer Healthcare Inc., at: 1-888-788-8181
www.voltaren.ca

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