

Part III: Consumer Information

Voltaren Emulgel Back & Muscle Pain

Diclofenac diethylamine gel 11.6 mg/g (1.16% w/w)
(No Mess Applicator)

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.

Separate Product Monograph available for **Voltaren Emulgel** Extra Strength and **Voltaren Emulgel** Joint Pain Extra Strength (Diclofenac diethylamine Gel, 23.2 mg/g (2.32% w/w)).

ABOUT THIS MEDICATION

What the medication is used for:

Voltaren Emulgel Back & Muscle Pain

- For the relief of pain associated with recent (acute), localized 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.
- Do not use right before or after heart surgery.

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 localized 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 and 150 g.

Voltaren Emulgel Back & Muscle Pain 1.16% w/w gel (No Mess Applicator) comes in tubes of 120 g.

The gel is white to practically 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, or think you may be pregnant, or are planning to have a baby, or are breastfeeding.
- 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.

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 (regular strength):

- Apply gel 3 to 4 times a day on the affected area.
- 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 cm² area. Do not use more than 4 times in 24 hours.
- Applicator: (See figure 1) To remove the seal before first use, remove the transparent protective cover and then unscrew the applicator cap. Use the star-shape groove (the key), located at the side of the applicator cap, to remove the security seal (star seal) of the tube. Screw the applicator cap back on the tube before dispensing the gel.
- Applicator: (See figure 1) To open, simply pull the white part of the applicator cap. Gently squeeze the tube to push the gel to the surface of the applicator cap. Use the applicator-capped tube as you would use your fingers to gently, and slowly rub the gel into the skin on the affected area. The slight pressure of rubbing in the gel will automatically close the applicator cap.
- You may notice a slight cooling effect when you rub the gel in.
- Applicator: (See figure 1) After use, clean the applicator cap 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 cap. After cleaning, place the transparent protective cap, back on the tube before storage. Do not reuse the applicator cap with another tube. Discard the tube with its applicator cap, following the recommended procedure for disposal of any medication.
- Wash your hands after rubbing in **Voltaren Emulgel** Back & Muscle Pain to avoid accidental contact with the mouth and eyes.

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



Using the key on the applicator cap, 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:

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 dispense more gel than needed, 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. Do not use after the expiry date stated on the label.

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

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

GlaxoSmithKline Consumer Healthcare Inc., Mississauga, ON L5N 6L4
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