

Voltaren[®] Emulgel

Diclofenac diethylamine gel 11.6 mg/g (1.16%)

This leaflet is part III of a three-part "Product Monograph" published when Voltaren Emulgel[®] 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[®]. **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:

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[®] 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 group 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 you are breast-feeding.

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:

Carbomer, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, liquid paraffin, macrogol cetostearyl ether, perfume (containing benzyl benzoate), 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[®] 1.16% gel comes in tubes of 20 g, 30 g, 50 g, 100 g and 150 g. The gel is white, cooling, non-greasy, non-staining, cream-like.

WARNINGS AND PRECAUTIONS

BEFORE you use Voltaren Emulgel[®] 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.
- You are taking, or have recently taken, any other medicines, including Over the Counter drugs.

Voltaren Emulgel[®] 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[®].

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[®] 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[®]:

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 cm² area.
- Tubes: before first use, unscrew and remove the cap. Use the reverse side of the cap to remove the seal from the tube.
- Gently squeeze out a small amount of gel from the tube and apply to the painful or swollen area, slowly rubbing into the skin. You may notice a slight cooling effect when you rub the gel in.
- Wash your hands after rubbing in Voltaren Emulgel[®] to avoid accidental contact with the mouth and eyes, unless of course they 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.

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.

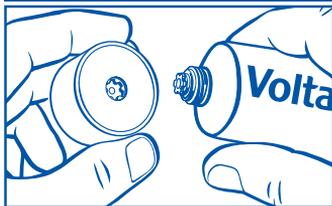
If you use more gel than you should wipe off the surplus gel with a tissue.

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

Missed Dose:

If you miss applying Voltaren Emulgel[®] at the correct time, apply it when you remember and then next apply it at the usual time. Do not apply a double quantity.

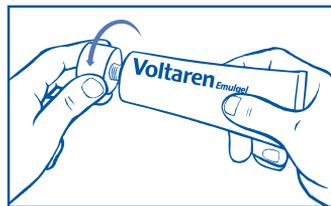
INSTRUCTIONS ON HOW TO OPEN THE TUBE



1. Take the lid off the tube. Open the safety seal by firmly pressing the indent on the outside of the lid onto the star-shaped seal on the tube.



2. Firmly turn the lid to remove the safety seal.
3. Do not open the safety seal with scissors or other sharp objects.



4. After use, put the cap back on the end of the tube and store in an upright position.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Itching, reddening or slight irritation of the skin are common after use of Voltaren Emulgel®. 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®, contact your doctor or pharmacist.

HOW TO STORE IT

Voltaren Emulgel® should be stored between 15°C and 30°C. Voltaren Emulgel® should not be stored or used after the expiry date shown on the carton and tube. Keep Voltaren Emulgel® out of the reach and sight of children.

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

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

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