

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

VOLTAREN EMULGEL EXTRA STRENGTH

Diclofenac diethylamine gel 23.2 mg/g (2.32% w/w), Mfr. Std.

Read this carefully before you start taking **Voltaren Emulgel Extra Strength** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Voltaren Emulgel Extra Strength**.

What is Voltaren Emulgel Extra Strength used for?

- 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.

How does Voltaren Emulgel Extra Strength work?

Voltaren Emulgel Extra Strength 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.

What are the ingredients in Voltaren Emulgel Extra Strength?

Medicinal ingredients: diclofenac, diethylamine

Non-medicinal ingredients: butylhydroxytoluene, carbomer, cocoyl caprylocaprate, diethylamine, fragrance, isopropyl alcohol, liquid paraffin, macrogol cetostearyl ether, oleyl alcohol, propylene glycol, purified water.

Propylene glycol may cause mild localized skin irritation in some people.

Butylhydroxytoluene may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

Voltaren Emulgel Extra Strength comes in the following dosage forms:

Voltaren Emulgel Extra Strength 2.32% w/w gel come in tubes of 30 g, 60 g and 100 g in a carton with a dosing card.

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

Do not use Voltaren Emulgel Extra Strength 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.
- In the past you have had allergic reactions to diclofenac or any other NSAIDs such as ibuprofen, ASA or naproxen.
- 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.
- You are allergic to any of the nonmedicinal ingredients in the gel (see list of non-medicinal ingredients).
- You are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery.
- You are about to have 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.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Voltaren Emulgel Extra Strength. Talk about any health conditions or problems you may have, including if you:

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

Other warnings you should know about:

Voltaren Emulgel Extra Strength is not intended for use in children under the age of 18.

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.

Do not use more than directed or for a longer than approved duration of use, unless under medical advice. Avoid applying on large areas of the skin.

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 Extra Strength.

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.

Wash your hands after use. 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 Extra Strength is for EXTERNAL USE ONLY.

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

Never swallow it.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

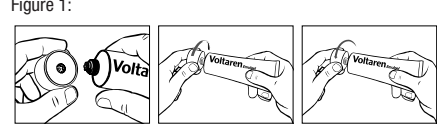
The following may interact with Voltaren Emulgel Extra Strength:

- 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.

How to take Voltaren Emulgel Extra Strength:

- To remove the security seal before first use, remove the cap off the tube. (see figure 1)
 - Firmly insert the star-shaped groove located on the reverse side of the cap into the star-shaped security seal of the tube. (see figure 1)
 - Firmly turn the cap to remove the security seal from the tube. (see figure 1)
 - Measure the amount of the gel using the dosing card and then gently apply to the affected area, slowly rubbing into the skin. You may notice a slight cooling effect when you rub the gel in.
 - After use, place the cap back on the tube and store in an upright position. (see figure 1)
 - After application wipe your hands with a tissue and then wash to avoid accidental contact with the mouth and eyes. The tissue should be thrown in the trash after use.
 - Wait until Voltaren Emulgel Extra Strength dries before showering or bathing.
- Do not throw away any medicines via wastewater (e.g. toilet or sink). Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Figure 1:



Usual dose:

For adults between 18 to 65 years (extra strength):

- Apply 2 g of gel 2 times a day (morning and evening) on the affected area.
- The amount of gel applied (2 g for each application) should be measured using the dosing card supplied in the product carton. For each application the gel should be squeezed from the tube and measured up to the 2 g line on the dosing card. Clean and dry the dosing card after each use.
- Do not use more than 4 g per day.

Use no more than is required for the shortest period of time needed. 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:

If you dispense more gel than needed, wipe off the surplus gel with a tissue.

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

If you think you, or a person you are caring for, have taken too much Voltaren Emulgel Extra Strength, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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

What are possible side effects from using Voltaren Emulgel Extra Strength?

These are not all the possible side effects you may have when taking Voltaren Emulgel Extra Strength. If you experience any side effects not listed here, tell your healthcare professional.

Itching, reddening or slight irritation of the skin are common after use of Voltaren Emulgel Extra Strength. 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 and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Skin rash, itching, reddening or smarting of the skin		✓	✓
RARE Some rare and very rare side effects might be serious			
Skin rash with blisters; hives		✓	✓
Swelling of the face, lips, tongue or throat		✓	✓
Wheezing, shortness of breath or feeling of tightness in the chest (asthma)		✓	✓
VERY RARE			
The skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering		✓	✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) 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.

Storage:

Store between 15°C and 30°C.

Voltaren Emulgel Extra Strength should not be stored or used after the expiry date shown on the label.

Keep out of reach and sight of children.

If you want more information about Voltaren Emulgel Extra Strength:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; or by calling 1-888-786-8181.

Separate Product Monograph available for VOLTAREN EMULGEL, VOLTAREN EMULGEL Back & Muscle Pain and VOLTAREN EMULGEL Joint Pain Regular Strength (Diclofenac diethylamine gel, 11.6 mg/g (1.16% w/w), Mfr. Std.)

This leaflet was prepared by GlaxoSmithKline Consumer Healthcare U.L.C.

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