



Patient Information Leaflet

VOLTAREN EMULGEL

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

20 g, 50 g - S0

100 g, 50 ml, 75 ml or 100 ml - S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Voltaren® Emulgel® (1,16 g diclofenac diethylamine corresponding to 1 g diclofenac sodium per 100 g gel).

Read all of this leaflet carefully because it contains important information for you

Voltaren Emulgel is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Voltaren Emulgel carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Voltaren Emulgel with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What Voltaren Emulgel is and what it is used for
2. What you need to know before you use Voltaren Emulgel
3. How to use Voltaren Emulgel
4. Possible side effects
5. How to store Voltaren Emulgel
6. Contents of the pack and other information

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1. WHAT VOLTAREN EMULGEL AND WHAT IT IS USED FOR

Voltaren Emulgel contains the active substance diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Voltaren Emulgel is specially formulated for rubbing into the skin.

Voltaren Emulgel is used to relieve pain and reduce inflammation and swelling in a number of painful conditions affecting the joints and muscles. It can be used to treat:

- muscle and joints injuries (e.g. sprains, strains, bruises, backache, sports injuries)
- tendonitis (e.g. tennis elbow)
- mild arthritis of the knee or fingers.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE VOLTAREN EMULGEL

Do not use Voltaren Emulgel if you:

- If you ever had an allergic reaction to diclofenac or other non-steroidal anti-inflammatory medicines used to treat pain, fever or inflammation, such as ibuprofen or aspirin (a substance also used to prevent blood clotting) or any other ingredients contained in this medicine. If you are not sure, ask your doctor or pharmacist.

Symptoms of an allergic reaction to these medicines may include: asthma, wheezing or shortness of breath; skin rash or hives; swelling of the face or tongue; runny nose • are using any other medicine containing diclofenac or are taking oral NSAIDs such as aspirin or ibuprofen

- have severe joint pain of recent onset that is not related to an injury or period of over-use.
- feel ill, have a temperature or any other symptoms that accompany the pain.
- are in the last 3 months of pregnancy
- Voltaren should not be used by patients with porphyria.

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Warnings and precautions

Take special care with Voltaren Emulgel:

- Do not apply Voltaren Emulgel to skin with conditions such as cuts, open wounds or on skin that has a rash or eczema.
- Be careful not to get Voltaren Emulgel in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.
- Voltaren Emulgel is for external use only. Do not use it in the mouth. Do not swallow it.
- Keep out of the sight and reach of children.
- Patients should be instructed to be cautious when smoking or near naked flames due to risk of severe burns. VOLTAREN EMULGEL contains paraffin which is potentially flammable when it builds up on fabric (clothing, bedding, dressings etc.). Washing clothing and bedding may reduce product build up but not totally remove it.

Taking other medicines with Voltaren Emulgel:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Pregnancy and Breastfeeding:

Voltaren Emulgel is not for use during the last 3 months of pregnancy, as it could harm your un-born child or cause problems at delivery.

Mothers using Voltaren Emulgel should not breastfeed their babies as diclofenac passes into breast milk.

Voltaren Emulgel should not be applied on the breasts of nursing mothers.

Consult your doctor or pharmacist for further information if you are pregnant or breast-feeding.

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Effects of other ingredients (excipients) Voltaren Emulgel contains:

- propylene glycol, which may cause a mild localised skin irritation in some people.

Important information about some of the ingredients of Voltaren Emulgel:

The gel formulation contains propylene glycol, which may cause a mild localised skin irritation in certain people.

3. HOW TO USE VOLTAREN EMULGEL

Always use Voltaren Emulgel exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you.

You should check with your doctor or pharmacist if you are not sure.

Do not share medicines prescribed for you with any other person.

For adults and adolescents over 12 years of age.

Apply Voltaren Emulgel 3 to 4 times a day on the painful area.

How to apply Voltaren Emulgel:

- To remove the seal before first use, unscrew and remove the cap. Use the reverse side of the cap to insert, twist and remove the seal from the tube.
- Gently rub a small amount of Voltaren Emulgel into the skin where you have pain or swelling. The amount needed will vary depending upon the size of the painful or swollen area. Usually, an amount ranging in size from a cherry to a walnut will be sufficient. You may notice a slight cooling effect when you rub the gel.
- Wash your hands after rubbing in Voltaren Emulgel, unless of course they are the site being treated.

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How long should you use Voltaren Emulgel:

- Do not use Voltaren Emulgel for more than 2 weeks for muscle and joints injuries (e.g. sprains, strains, bruises) or tendonitis, or 3 weeks for arthritis pain, unless longer treatment is recommended by a doctor.
- If the pain and swelling do not improve within 7 days, or if they get worse, tell your doctor.

If you use more Voltaren Emulgel than you should:

In the event of overdosage, wipe off the surplus gel with a tissue and consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use Voltaren Emulgel:

If you miss applying Voltaren Emulgel at the correct time, apply it as soon as possible and then carry on as normal. Do not apply a double quantity.

If you accidentally swallow Voltaren Emulgel:

Seek medical advice immediately in case of accidental swallowing.

4. POSSIBLE SIDE EFFECTS

Voltaren Emulgel can have side effects.

Some rare and very rare side effects might be serious.

If you experience any of the following signs of allergy, STOP using Voltaren Emulgel and tell a doctor or pharmacist immediately:

- Skin rash with or without blisters; hives. These are likely to affect 1 to 10 people out of 10,000.

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- Wheezing, shortness of breath or feeling of tightness in the chest (asthma). These are likely to affect less than 1 person out of 10,000.
- Swelling of the face, lips, tongue or throat. These are likely to affect less than 1 person out of 10,000.

Less serious side effects

Other side effects which may occur are usually mild, passing and harmless. If you are concerned, tell a doctor or pharmacist as soon as you can.

- Skin rash, itching, reddening or smarting of the skin are common after use. These side effects are likely to affect 1 to 10 people out of 100.
- In very rare cases, the skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering. This is likely to affect less than 1 person out of 10,000.

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> . By reporting side effects, you can help provide more information on the safety of Voltaren Emulgel.

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5. STORING AND DISPOSING OF VOLTAREN EMULGEL

- Keep Voltaren Emulgel out of the reach and sight of children.

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- Store at or below 25 °C. Protect the pressurized containers from direct sunlight and do not pierce or burn even when empty.
- Do not use after the expiry date shown on the carton and tube or pump dispenser.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. WHAT IS IN THE PACK AND FURTHER INFORMATION

WHAT VOLTAREN EMULGEL CONTAINS

The active substance is diclofenac diethylamine 1,16 g corresponding to 1 g diclofenac sodium per 100 g.

The base is a fatty emulsion containing isopropanol and propylene glycol, in an aqueous gel.

The other ingredients are carbomer 974 P, cocoyl caprylocaprate, purified water, diethylamine, liquid paraffin, macrogol cetostearyl ether, perfume cream 45.

What Voltaren Emulgel looks like and contents of the pack

20 g, 50 g and 100 g Aluminium laminated tubes with white or blue polypropylene caps.

Pressurised aluminium 50 ml, 75 ml or 100 ml containers containing a multilayer pouch (low density polyethylene layer in contact with the product) with a high-density polyethylene/titanium oxide valve and polyoxymethylene actuator with protective cap.

Voltaren Emulgel is a white, cooling, non-greasy, non-staining cream-like gel.

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7. HOLDER OF CERTIFICATE OF REGISTRATION HOLDER

GlaxoSmithKline Consumer Healthcare SA (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1

Cape Town, 7460

Tel: 011 745 6000

8. DATE OF PUBLICATION

Date of Registration: 16 April 1991

Date of latest revision of the text as approved by the authority: 27 October 2022

7. REGISTRATION NUMBER

U/3.1/77

Additional countries registration details:

<u>Country</u>	<u>Scheduling status (or Category of distribution)</u>	<u>Registration no.</u>
Botswana	S3	B9305535
Namibia	NS1	04/3.1/0344
Zambia	POM	242/015
Zimbabwe	P	87/3.1/2128

ATC Code: M02AA15 – Anti-inflammatory preparations, non-steroids for topical use

Pharmacological classification: 3.1 – Nonsteroidal anti-inflammatory medicines (Zimbabwe)

V1(13/06/2022)

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Name and address of manufacturer:

GSK Consumer Healthcare SARL
Route de l'Etraz 2,
CH-1260, Nyon,
Switzerland

Or

Purna Pharmaceuticals NV
Rijksweg 17,
B-2870 Puurs,
Belgium

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REF-78858