Final Approved Patient Information Leaflet

Voltaren Emulgel 12 Hour

SCHEDULING STATUS:

S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Voltaren Emulgel 12 Hour (gel)

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

Voltaren Emulgel 12 Hour is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Voltaren Emulgel 12 Hour carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Voltaren Emulgel 12 Hour with any other person.
- Ask your health care provider or 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 12 Hour is and what it is used for

2. What you need to know before you use Voltaren Emulgel 12 Hour

3. How to use Voltaren Emulgel 12 Hour

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1. What Voltaren Emulgel 12 Hour is and what it is used for

Voltaren Emulgel 12 Hour contains the active substance diclofenac which belongs to a group of medicines called non-steroidal anti- inflammatory drugs (NSAIDs). It is specially formulated for rubbing into the skin.

Voltaren Emulgel 12 Hour is used to relieve pain and reduce inflammation and swelling in a number of painful conditions affecting the joints and muscles. Voltaren Emulgel 12 Hour can be used to treat:

- muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries), relieving pain and helping recovery back to normal function;
- swelling around elbow or knee.
- Voltaren Emulgel 12 Hour is intended for use in adults and children aged 14 years and older.

2. What you need to know about Voltaren Emulgel 12 Hour Gel:

Do not use Voltaren Emulgel 12 Hour if you:

- are hypersensitive (allergic) to diclofenac or any of the other ingredients of Voltaren Emulgel 12 Hour or other medicines used to treat pain, fever or inflammation, such as ibuprofen or aspirin (a substance also used to prevent blood clotting), or any of the other ingredients of -Voltaren Emulgel 12 Hour (see Section 6 and end of Section 2). If you are not sure, ask your doctor or pharmacist.

  Symptoms of an allergic reaction may include: wheezing or shortness of breath (asthma);

  skin rash with blisters 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 overuse.
- feel ill, have a temperature or any other symptoms that accompany the pain.
- are in the last 3 months of pregnancy

If any of these apply to you, do not use Voltaren Emulgel 12 Hour Gel.

Warnings and precautions

Take special care with Voltaren Emulgel 12 Hour Gel

- Do not apply the gel to skin that has (i) a rash or eczema (ii) cuts or open wounds. Stop the treatment if a skin rash develops after applying the product. Avoid applying on large areas of skin and over a prolonged period of time, unless under medical advice.
- Voltaren Emulgel 12 Hour is for external use only. Do not use it in the mouth. Do not swallow it. Wash your hands after use unless they are the area to be treated. Be careful not to get Voltaren Emulgel 12 Hour in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.
- A brace or wrap commonly used for injuries like sprains can be used, but do not use the gel under airtight (plastic) bandages.
- If you have a stomach or duodenal ulcer (or a history of), tell your doctor or pharmacist before using the gel.
- If you have or have ever had asthma speak to your doctor or pharmacist before using the gel.

If you have any questions, talk to your doctor or pharmacist before using Voltaren Emulgel 12 Hour Gel.

Voltaren Emulgel 12 Hour is not recommended for use in children under 14 years of age.

Taking other medicines with Voltaren Emulgel 12 Hour Gel

- Please tell your doctor or pharmacist if you are taking, or have recently taken, or want to start taking any other medicines, including those obtained without a medical prescription.

Pregnancy and breast-feeding

Voltaren Emulgel 12 Hour is not for use during the last 3 months of pregnancy, as it could harm your unborn child

or cause problems at delivery.

Mothers using Voltaren Emulgel 12 Hour should not breastfeed their babies as diclofenac passes into breast milk.

Voltaren Emulgel 12 Hour 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.

Effects of other ingredients (excipients) Voltaren Emulgel 12 Hour contains:

- propylene glycol, which may cause a mild localised skin irritation in some people.
- butylhydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

3. How to use Voltaren Emulgel 12 Hour Gel

Always use Voltaren Emulgel 12 Hour Gel 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.

How much Voltaren Emulgel 12 Hour to use

For adults and adolescents 14 years and over.

- Apply the gel 2 times a day (preferably morning and evening) on the painful area.

How to apply Voltaren Emulgel 12 Hour Gel

1. 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.
2. Gently squeeze out a small amount of gel from the tube and apply to the painful or swollen area, slowly rubbing into the skin. The amount needed will vary depending upon the size of the painful or swollen area; an amount ranging in size from a 1 penny to a 2 pence piece will usually be sufficient (2–4g). You may notice a slight

cooling effect when you rub the gel in. Only use the smallest amount of Voltaren Emulgel 12 Hour needed to relieve your pain but never use more than 8g per day and 56g in one week.

3. Unless the hands are the site being treated, wash your hands after rubbing in the gel, to avoid accidental contact with the mouth and eyes. (see Section 2).

Voltaren Emulgel 12 Hour is for external use only.

How long to use Voltaren Emulgel 12 Hour for

Do not use Voltaren Emulgel 12 Hour for more than 7 days 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.

In children aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

If you use more Voltaren Emulgel 12 Hour than you should

- 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.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use Voltaren Emulgel 12 Hour Gel

If you miss your application of Voltaren Emulgel 12 Hour at the correct time, apply it when you remember and then carry on as normal.

Do not apply a double quantity to make up for the forgotten application. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Voltaren Emulgel 12 Hour can have side effects.

Not all side effects reported for Voltaren 12 Hour are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Voltaren 12 Hour, please consult your healthcare provider for advice.

Some less frequent side effects might be serious

If any of the following happens, stop taking / using Voltaren 12 Hour and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Skin rash with blisters; hives. (These side effects are frequent).
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma). (These side effects are less frequent.
- Swelling of the face, lips, tongue or throat. (These side effects are likely to affect less than 1 person in every 10,000).

These are all very serious side effects. If you have them, you may have had a serious reaction to Voltaren 12 Hour. You may need urgent medical attention or hospitalization.

Tell your doctor if you notice any of the following:

Frequent side effects

(likely to affect between 1 and 10 in every 100 patients)

- Skin rash, itching, reddening or smarting of the skin

Less frequent side effects

(likely to affect less than 1 in every 10,000 patients)

- The skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering.

If you notice any side effects not mentioned in the leaflet, please inform 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 12 Hour Gel.

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5. How to store Voltaren Emulgel 12 Hour Gel

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Do not use Voltaren Emulgel 12 Hour after the expiry date which is stated on the carton and tube after EXP.
- Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. What is in the pack and further information

What Voltaren Emulgel 12 Hour contains

The active substance is diclofenac diethylammonium. Each gram of gel contains 23.2mg of diclofenac diethylammonium.

The other ingredients (excipients) are butylhydroxytoluene, carbomer, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, liquid paraffin, macrogol cetostearyl ether, oleyl alcohol, propylene glycol, perfume and purified

water (see end of Section 2 for further information).

What Voltaren Emulgel 12 Hour looks like and contents of the pack

Voltaren Emulgel 12 Hour is a white to practically white, cooling, non-greasy, non-staining cream-like gel.

The product comes in packs of 50 g and 100 g. Not all pack sizes may be marketed.

Holder of certificate of registration

GlaxoSmithKline Consumer Healthcare South Africa (Pty) Limited

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