Package leaflet: Information for the user
Voltarol Emulgel Extra Strength 2% w/w Gel
diclofenac diethylammounium 2.32% w/w corresponding to diclofenac sodium 2% w/w (20mg/g)

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use **Voltarol Emulgel Extra Strength 2% w/w Gel** carefully to get the best results from it.
Always use this medicine exactly as described in this leaflet.
• Keep this leaflet. You may need to read it again.
• Ask your pharmacist if you need more information or advice.
•You must contact a doctor if your signs of illness worsen or do not improve within 7 days.
• If you get any side effects which worry you (even side effects not listed in this leaflet), talk to your doctor or pharmacist.

What is in this leaflet

1. What **Voltarol Emulgel Extra Strength 2% w/w Gel** is and what it is used for
2. What you need to know before you use **Voltarol Emulgel Extra Strength 2% w/w Gel**
3. How to use **Voltarol Emulgel Extra Strength 2% w/w Gel**
4. Possible side effects
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6. Contents of the pack and other information

1.What Voltarol Emulgel Extra Strength 2% w/w Gel is and what it is used for

Voltarol Emulgel Extra Strength 2% w/w Gel 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 and has enhanced skin permeation. The active substance targets deep inflamed tissues.

Voltarol Emulgel Extra Strength 2% w/w Gel is used to relieve pain and reduce inflammation and swelling in a number of painful conditions affecting the joints and muscles, e.g. sprains, strains and bruises, relieving pain quickly, including moderate to strong pain, and helping recovery to normal function.

2. What you need to know before you use Voltarol Emulgel Extra Strength 2% w/w Gel

Do not use Voltarol Emulgel Extra Strength 2% w/w Gel
• if you are allergic (hypersensitive) to diclofenac 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 this medicine (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.
• if you are in the last 3 months of pregnancy.
• if you are below 14 years of age.
If any of these apply to you, do not use Voltarol Emulgel Extra Strength 2% w/w Gel

Take special care with Voltarol Emulgel Extra Strength 2% w/w Gel

• Do NOT apply to skin with conditions such as cuts, open wounds, or on skin that has a rash or eczema. Discontinue the treatment if a skin rash develops after applying the product.
• A brace or wrap commonly used for injuries like sprains can be used but do not use under airtight (plastic) bandages.
• **Avoid applying on large areas of skin** and over a prolonged period of time, unless under medical advice.
• Use of the gel over extensive areas of skin for a prolonged time or using more than the recommended dose may give some side effects. Symptoms include: gastrointestinal disturbances and bleeding, irritability, fluid retention, rash, liver inflammation, kidney problems, allergic reactions, difficulty in breathing and skin lesions.
•**Voltarol Emulgel Extra Strength 2% w/w Gel** is for use only on the skin. Do not use it in the mouth. Do not swallow it.Wash your hands after use. Be careful not to get **Voltarol Emulgel Extra Strength 2% w/w Gel** in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.
• Your skin may be more sensitive to sunlight. Be careful when sunbathing or using sun lamps.
• If you have, or have had, peptic ulcers, gastrointestinal bleeding, liver or kidney problems, certain blood disorders, asthma or intestinal inflammation, tell your doctor or pharmacist.
• Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.
If you have any questions, talk to your doctor or pharmacist before using Voltarol Emulgel Extra Strength 2% w/w Gel.

Other medicines and Voltarol Emulgel Extra Strength 2% w/w 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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Voltarol Emulgel Extra Strength 2% w/w Gel must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. **Voltarol Emulgel Extra Strength 2% w/w Gel** should only be used under medical advice during the first 6 months of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

Voltarol Emulgel Extra Strength 2% w/w Gel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, **Voltarol Emulgel Extra Strength 2% w/w Gel** should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period of time.

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

Oral forms (e.g. tablets) of diclofenac can cause adverse effects in your unborn baby. It is not known if the same risk applies to diclofenac when it is used on the skin.

Driving and Using Machines
Voltarol Emulgel Extra Strength 2% w/w Gel, when used as directed, is not expected to have any effect on your ability to drive or use machines.

Important information about some of the ingredients of Voltarol Emulgel Extra Strength 2% w/w Gel
Voltarol Emulgel Extra Strength 2% w/w Gel contains:
• **propylene glycol,** which may cause skin irritation.
• **butylhydroxytoluene,** which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.
This medicine contains fragrance with **limonene** and **linalool,** which may cause allergic reactions.

3. How to use Voltarol Emulgel Extra Strength 2% w/w Gel

Always use this medicine exactly as described in this leaflet or as advised by your doctor or pharmacist. This gel is for use only on the skin (cutaneous use).

For adults and adolescents over 14 years of age.
Apply the gel 2 times a day (preferably morning and evening) on the painful area.

How to apply Voltarol Emulgel Extra Strength 2% w/w Gel
Do not use if tamper evident seal is broken.

1. a) **For the flip-top lid cap:**
Use a finger, thumb, side of your hand or even edge of a table against the underside of the cap lid to open the flip-top cap easily.
b) **For the screw cap:**
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 cherry to a walnut will usually be sufficient. You may notice a slight cooling effect when you rub the gel in.
3. Afterwards, the hands should be wiped with a paper towel and then washed, unless the hands are the area to be treated. Also after use, if needed, remove remaining amount of the gel from the flip-top cap with a paper towel until visibly clean and dry. Close the flip-top cap, until you hear a 'click' sound. Hold the tube upright when opening or closing the flip-top cap to avoid possible leaking of the gel.
4. If too much gel is accidently applied, the excess gel should be wiped away with a paper towel. The paper towel should be disposed in the household waste to prevent unused product reaching the aquatic environment.
5. Before applying a bandage, the gel should be left to dry for a few minutes on the skin.

c) **For the snapped-on applicator cap:**

1) Hold the tube upright and use a finger, thumb, side of your hand to open the cap lid until it clicks in place. Tamper evident tab located on the left side of the cap will break when it is opened for the first time. Check that the tab is not broken before you first use it.



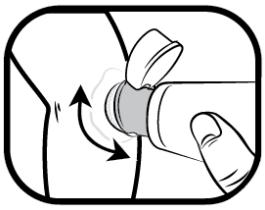


2) Push the applicator head upwards before use.



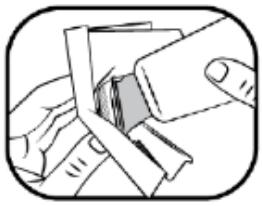
3) Gently press the tube so that the gel comes out onto the surface of the applicator. The amount needed will vary depending upon the size of the painful or swollen area. An amount ranging in size from a cherry to a walnut will usually be sufficient. Apply the gel directly to the painful area using the applicator, without getting it on your hands, unless they are the area to be treated. Gently massage into the skin.





You may notice a slight cooling effect when you rub the gel in.

4) After use:
   a. If needed, clean the cap with a paper towel to remove any remaining gel from the cap. The paper towel should be disposed in the household waste to prevent unused product reaching the aquatic environment.



   b. To close the cap lid, hold the tube upright and press it down, until it clicks in place.



   c. Before dressing or applying a non-airtight bandage, let the gel dry for a few minutes on the skin.

How long to use Voltarol Emulgel Extra Strength 2% w/w Gel for

You should not use this gel for more than **14 days**. If the pain and swelling **do not improve within 7 days**, or if they get worse, **tell your doctor.**
In adolescents 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 Voltarol Emulgel Extra Strength 2% w/w Gel than you should
If you use more gel than you should, wipe off the surplus gel with a paper towel.
If you or a child accidentally swallows the gel, contact your doctor immediately.

If you forget to use Voltarol Emulgel Extra Strength 2% w/w Gel
If you miss your application of **Voltarol Emulgel Extra Strength 2% w/w Gel** at the correct time, apply it as soon as you remember 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
Like all medicines, **Voltarol Emulgel Extra Strength 2% w/w Gel** can cause side effects, although not everybody gets them.
Some rare and very rare side effects might be serious
If you experience any of the following signs of allergy, STOP using **Voltarol Emulgel Extra Strength 2% w/w Gel** and tell a doctor or pharmacist immediately:

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

Other side effects which may occur are usually mild, passing and harmless *(if you are concerned, tell a doctor or pharmacist).*
Common side effects (may affect between 1 and 10 in every 100 people)

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

Very rare side effects (may affect up to 1 in 10,000)

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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Voltarol Emulgel Extra Strength 2% w/w Gel

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Voltarol Emulgel Extra Strength 2% w/w Gel contains
The active substance is diclofenac diethylammonium. The gel contains diclofenac diethylammonium 2.32% w/w corresponding to diclofenac sodium 2% w/w (20mg/g).

The other ingredients are butylhydroxytoluene [E 321], carbomer, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, liquid paraffin, macrogol cetostearyl ether, oleyl alcohol, propylene glycol [E 1520], perfume eucalyptus sting (including limonene and linalool), and purified water (see end of Section 2 for further information). **Voltarol Emulgel Extra Strength 2% w/w Gel** contains 50 mg propylene glycol and 0.2 mg butylhydroxytoluene in each gram of gel.

What Voltarol Emulgel Extra Strength 2% w/w Gel looks like and contents of the pack
Voltarol Emulgel Extra Strength 2% w/w Gel is a white, pleasantly perfumed, non-greasy, cream-like gel. The product is supplied in either an aluminium-laminated tube with a polypropylene screw cap in pack sizes of 20 g, 30 g, 50 g and 100 g, or a flip top cap in a pack size of 100 g, or a snapped-on applicator cap in a pack size of 100 g.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland.

Manufacturer
Haleon Germany GmbH, Barthstraße 4 80339 Munich, Germany.

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