Package leaflet: Information for the user

Voltarol 1% w/w Gel
diclofenac diethylammonium 1.16% w/w corresponding to diclofenac sodium 1 % w/w (10 mg/g)

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.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, talk you your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Voltarol 1% w/w Gel is and what it is used for
Voltarol 1% w/w Gel contains the active ingredient diclofenac which is from the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Voltarol 1% w/w Gel is used to relieve pain and reduce swelling in a number of painful conditions affecting the joints and muscles, e.g. sprains, strains and bruises. It is also used to relieve the pain of arthritis in joints.

2. What you need to know before you use Voltarol 1% w/w Gel

DO NOT use Voltarol 1% w/w Gel if you:
• are allergic (hypersensitive) to diclofenac, propylene glycol, isopropyl alcohol or any of the other ingredients in the product (see Section 6)
• have ever had an allergic reaction to diclofenac or other medicines used to treat pain, fever or inflammation, such as ibuprofen or aspirin. 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 asthmatic and are allergic (hypersensitive) to aspirin or other non-steroidal agents, such as ibuprofen
• are in the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.
• are below 14 years of age.

Take special care with Voltarol 1% w/w Gel
• Do NOT apply to skin with conditions such as cuts, open wounds, or on skin that has a rash or eczema.
• Do not cover with bandages.
• Discontinue the treatment if a skin rash develops after applying the product.
• This gel is for use only on the skin. Do not use it in the mouth. Do not swallow it. Be careful not to get the gel in your eyes or the inside of your nose. If you get the gel in your eyes, rinse them well with clean water. See your doctor or pharmacist if any discomfort
• 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.

• 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.

Taking other medicines
Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including those obtained without a 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 1% 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 1% 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 1% w/w Gel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Voltarol 1% 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.

Driving and using machines

Voltarol 1% 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 1% w/w Gel

Voltarol 1% w/w Gel contains **propylene glycol** and **benzyl benzoate**, which may cause skin irritation.

3. How to use Voltarol 1% w/w Gel

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

Adults and adolescents 14 years and over:
1. Before using for the first time, open as follows:
Unscrew cap and pierce the aluminium seal with the spiked top of the cap. Do not use if seal is broken.2. Gently rub a small amount of gel into the skin around the painful or swollen area. The amount of gel needed will vary depending upon the size of the painful or swollen area. Usually, a quantity the size of a cherry or a walnut will be sufficient.
3. You can apply the gel 3 to 4 times a day unless your doctor or pharmacist tells you otherwise. You may notice a slight cooling effect when you rub the gel into the skin. Do not rub the gel into cuts, open wounds or any other area where the skin is abnormal.
4. After rubbing the gel into the skin, do not cover with bandages or sticking plaster.
5. Be careful not to get the gel in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.
6. Wash your hands after rubbing in the gel (unless they are the site being treated).

Strains, sprains and bruises will normally improve within 2 weeks. If they do not, or your symptoms get worse, tell your doctor.

If you are using Voltarol Gel for arthritis, your doctor may wish to review your treatment regularly.

You should not use this gel for more than 14 days. If your symptoms get worse or do not improve, 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.

Children: Voltarol Gel is not suitable for children under 14 years of age.

If you use more Voltarol 1% w/w Gel than you should
If you use more Voltarol 1% w/w Gel than you should, wipe off the surplus gel with a tissue.
If you or a child accidentally swallows Voltarol 1% w/w Gel, contact your doctor or accident and emergency department immediately.

If you forget to use Voltarol 1% w/w Gel
If you miss your application of Voltarol 1% 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 a forgotten application. If you have any further questions on the use of this product, ask your pharmacist.

4. Possible side effects

Like all medicines, Voltarol 1% w/w Gel can cause side effects, although not everybody gets them.

Some rare and very rare side effects might be serious
STOP using Voltarol 1% w/w Gel and tell a doctor or pharmacist immediately if you experience any of the following signs of an allergic reaction:

- Skin rash with blisters; hives *(may affect between 1 and 10 in every 10,000 people).*
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma) (*may affect less than 1 in every 10,000 people).*
- Swelling of the face, lips, tongue or throat (*may affect less than 1 in every 10,000 people).*

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 affects less than 1 in every 10,000 people)*

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

Asthma has been rarely reported in patients using topical NSAID preparations.

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 1% w/w Gel
Keep out of the sight and reach of children.
Do not store above 30°C.
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.

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 1% w/w Gel contains
The **active substance** is diclofenac diethylammonium (equivalent to 1g of diclofenac sodium in each 100g of gel).

The **other ingredients** are diethylamine, carbomer, macrogol cetostearyl ether, cocoyl caprylocaprate, isopropyl alcohol, liquid paraffin, propylene glycol, purified water, perfume (containing benzyl benzoate). This medicine contains 50mg propylene glycol and 1mg benzylbenzoate in each gram gel. For further information on propylene glycol and benzyl benzoate see end of section 2 'Important information about some of the ingredients'.

What Voltarol 1% w/w Gel looks like and contents of the pack
Voltarol 1% w/w Gel is a white, pleasantly perfumed, non-greasy cream-like gel, packed inside an aluminium tube or aluminium laminate tube with plastic screw cap. This is supplied in a carton and comes in packs of 30g and 50g. Not all pack sizes may be marketed.

Marketing authorisation holder
Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Manufacturer
Haleon Germany GmbH or GlaxoSmithKline Consumer Healthcare GmbH & Co. KG Barthstraße 4 80339 Munich, Germany.

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