

Patient Information Leaflet

Voltarol

3

Back and Muscle Pain Relief 1.16% Gel

Diclofenac diethylammonium

• Relieves pain • Reduces inflammation • Cools skin



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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 Back and Muscle Pain Relief 1.16% Gel carefully to get the best results from it.

- 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 symptoms worsen or do not improve within 7 days.**
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Voltarol Back and Muscle Pain Relief 1.16% Gel is and what it is used for

Voltarol Back and Muscle Pain Relief 1.16% 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 is used to relieve pain and reduce inflammation and swelling in painful conditions affecting the joints and muscles. Voltarol Back and Muscle Pain Relief 1.16% Gel can be used to treat:

- muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries)
- tendonitis (e.g. tennis elbow)

2. Before you use Voltarol Back and Muscle Pain Relief 1.16% Gel

DO NOT use Voltarol Back and Muscle Pain Relief 1.16% Gel if you:

- have an allergy (hypersensitivity) to any of the ingredients in the product (*see Section 6 'What Voltarol Back and Muscle Pain Relief 1.16% Gel contains'*).
- have ever had an allergic reaction to diclofenac or other medicines used to treat pain, fever or inflammation, such as aspirin (acetylsalicylic acid) or ibuprofen. 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 in the last 3 months of your pregnancy (see also pregnancy and breast-feeding section).
- are using any other medicine containing diclofenac or are taking oral NSAIDs such as aspirin or ibuprofen.

This medicine is not recommended for use in children under 14 years of age.

Take special care with Voltarol Back and Muscle Pain Relief 1.16% 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.
- Be careful when sunbathing or using sun lamps as your skin may be more sensitive to sunlight.
- 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.

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. Do not use Voltarol Back and Muscle Pain Relief 1.16% Gel if you are already taking diclofenac tablets or other NSAID pain/inflammation tablets (e.g. aspirin or ibuprofen).

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 Back and Muscle Pain Relief 1.16% 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 Back and Muscle Pain Relief 1.16% 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 Back and Muscle Pain Relief 1.16% Gel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Voltarol Back and Muscle Pain Relief 1.16% 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 breastfeeding.

Driving and using machines

Voltarol Back and Muscle Pain Relief 1.16% 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 Back and Muscle Pain Relief 1.16% Gel

The gel formulation contains propylene glycol and benzyl benzoate, which may cause mild localised skin irritation in some people.

3. How to use Voltarol Back and Muscle Pain Relief 1.16% Gel

- Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.
- The gel is for external use only. Do not use it in your mouth. Inform your doctor immediately in case of accidental swallowing.
- Do not put Voltarol Back and Muscle Pain Relief 1.16% Gel in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.

Adults and adolescents 14 years and over

1. Take the tube out of the carton:
 - a. For the laminated tube: Unscrew and remove cap. When using for the first time, reverse the cap, engage with the nozzle, twist and remove the seal from the tube. Do not use if seal is broken.
 - b. For laminated tube with no mess applicator: To remove the seal before first use, remove the transparent protective cover and then unscrew the applicator. Use the star-shape groove located at the side of the applicator to remove the tamper evidence seal of the tube. Screw the applicator back on the tube before dispensing the gel. To open, pull the white part of the applicator. Gently squeeze the tube to push the gel to the surface of the applicator and gently rub the gel into the skin at the painful or swollen area. The slight pressure of rubbing in the gel will automatically close the applicator.
2. Gently squeeze out a small amount of gel from the tube and apply to the painful or swollen area 3 to 4 times a day, slowly rubbing into the skin. The amount needed will vary depending on 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. You may notice a slight cooling effect when you rub the gel in.
3. **Allow at least 4 hours between applications of the gel. Do not apply more than 4 times in any 24 hour period.**
4. Do not rub the gel into cuts, open wounds or any other area where the skin is abnormal. 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.

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Pharma code 1006

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6. Wash your hands after rubbing in Voltarol Back and Muscle Pain Relief 1.16% Gel, unless your hands are the site being treated. Replace the cap. For laminated tube with no mess applicator: After use, clean the applicator with cotton towel or absorbent paper until visually dry and clean. Do not immerse or rinse under water. Do not use any solvent or detergent to clean the surface of the applicator. After cleaning, place the transparent protective cap back on the tube before storage. Do not reuse the applicator with another tube.
7. In addition to applying the gel, the guidelines (known as "RICE") may be useful to help healing of sprains. See the end of this leaflet.

For Laminated tube with no mess applicator



1. Pull off the transparent protective cover



2. Unscrew the applicator cap



3. Using the key on the applicator cap to remove the star seal on the tube



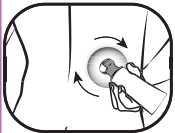
4. Screw the applicator cap back on the tube



5. Pull white part to open



6. Squeeze the tube to release required amount of Gel



7. Apply to skin, closing cap on application



8. Clean the applicator with cotton towel or absorbent paper until visually dry and clean

This medicine is not recommended for use in children under 14 years of age.

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.

Do not use Voltarol Back and Muscle Pain Relief 1.16% Gel 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 worsen, speak to your doctor. If symptoms do not improve within this time, or they get worse, consult your doctor.

If you use more Voltarol Back and Muscle Pain Relief 1.16% Gel than you should

If you or a child accidentally swallows Voltarol Back and Muscle Pain Relief 1.16% Gel, contact your doctor or accident and emergency department immediately.

If you forget to use Voltarol Back and Muscle Pain Relief 1.16% Gel

If you miss your application of Voltarol Back and Muscle Pain Relief 1.16% 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 Back and Muscle Pain Relief 1.16% 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 Back and Muscle Pain Relief 1.16% Gel and tell a doctor or pharmacist immediately:

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 affect less than 1 in every 10,000 people*) 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 the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Voltarol Back and Muscle Pain Relief 1.16% Gel

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use Voltarol Back and Muscle Pain Relief 1.16% Gel after the expiry date stated on the carton and tube. Medicines should not be disposed of 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. Further information

What Voltarol Back and Muscle Pain Relief 1.16% Gel contains

The **active substance** is diclofenac diethylammonium (1.16%) equivalent to 1g of diclofenac sodium in each 100 g of gel.

The **other ingredients** are carbomers, cetomacrogol, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, propylene glycol, liquid paraffin, perfume (contains benzyl benzoate), purified water (*see end of Section 2 'Important information about some of the ingredients of Voltarol Back and Muscle Pain Relief 1.16% Gel' for propylene glycol*).

What Voltarol Back and Muscle Pain Relief 1.16% Gel looks like and contents of the pack

Voltarol Back and Muscle Pain Relief 1.16% Gel is a white, cooling, non-greasy, non-staining cream-like gel, packed inside an aluminium or aluminium laminated tube with plastic screw cap or a cap applicator. This is supplied in a carton and comes in packs of 10g, 20g, 30g, 40g, 50g, 60g, 100g or 120g. (not all pack sizes may be marketed). Aluminium laminated tube with cap applicator comes in a pack of 100g.

Marketing authorisation holder and Manufacturer

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

RICE advice:

In addition to applying the gel, these guidelines (known as "RICE") may be useful to help healing of sprains.

Day 1 to Day 3

REST	Stop using the injured joint as much as possible in the first 48 hours. If you are unable to use the joint, e.g. put any weight at all on an ankle, it may be broken, so see a doctor as soon as possible so that an X-ray can be done
ICE	To decrease both swelling and pain, take a bag of ice (or frozen vegetables), wrap it in a towel, and apply for 10-20 minutes (longer may cause frostbite). Do this every hour, or at least 3 times a day.
COMPRESSION	Lightly wrap your joint/the affected area with an elastic bandage, make sure it is not so tight that it cuts off circulation to your limb.
ELEVATION	If possible raise the affected limb as much as possible in the first 48 hours to reduce swelling and pain

This leaflet was last revised in August 2018.