

Package leaflet: Information for the user

Voltarol Osteoarthritis Joint Pain Relief 1.16% Gel

Diclofenac diethylammonium

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 Osteoarthritis Joint 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 Osteoarthritis Joint Pain Relief 1.16% Gel is and what it is used for

Voltarol Osteoarthritis Joint 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 Osteoarthritis Joint 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)
- mild arthritis (symptoms of mild arthritis include joint pain at rest, joint pain on movement, joint swelling or stiffness (after sleep or long rest)).

2. Before you use Voltarol Osteoarthritis Joint Pain Relief 1.16% Gel

DO NOT use Voltarol Osteoarthritis Joint Pain Relief 1.16% Gel if you:

- have an allergy (hypersensitivity) to any of the ingredients in the product (see Section 6 'What Voltarol Osteoarthritis Joint 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 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.

- 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 your pregnancy (see also pregnancy and breast-feeding section).

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

Take special care with Voltarol Osteoarthritis Joint 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.
- Due to an increased possibility of side effects, take care if you are using any other medicine containing diclofenac or painkillers known as NSAIDs, such as aspirin or ibuprofen.
- 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.
- 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 Osteoarthritis Joint Pain Relief 1.16% Gel must not be used during the last 3 months of pregnancy, as it could harm your unborn child. Voltarol Osteoarthritis Joint 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 Osteoarthritis Joint 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 Osteoarthritis Joint 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.

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 Osteoarthritis Joint 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 Osteoarthritis Joint 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 Osteoarthritis Joint 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.

Adults and children 14 years and over:

Before using for the first time, open as follows:

- **aluminium tube:** Unscrew cap and pierce the aluminium seal with the spiked top of the cap. Do not use if seal is broken.
- **laminated tube:** Unscrew cap and remove. Reverse the cap, engage with the nozzle, twist and remove the plastic seal from the tube. Do not use if seal is broken.
- **dispenser:** Remove the lid from the top of the dispenser.

How to apply:

Gently squeeze out a small amount of gel from the tube or press firmly and evenly on the nozzle of the dispenser and apply to the painful or swollen area, slowly rubbing into the skin.

When and how much to use:

- Apply 3 to 4 times a day. Allow at least 4 hours between applications of the gel. Do not apply more than 4 times in any 24 hour period.
- 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 (2 to 4g) will usually be sufficient.
- You may notice a slight cooling effect when you rub the gel in.
- Only use the smallest amount of Voltarol Osteoarthritis Joint Pain Relief 1.16% Gel needed to relieve your pain but never use more than 16g per day and 112g in one week.

How and where to use:

- You can apply the gel to a maximum of 2 joints (such as your knees or elbows). If you need to apply it to more than 2 joints, consult your doctor.
- 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.
- Use this medicine only on your skin. Do not use it in your mouth.
- Be careful not to get the gel in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.

After application:

Unless they are the site being treated, the hands should be wiped with a tissue and then washed, to avoid accidental contact with the mouth and eyes. The tissue should be disposed of in the household waste and not in the toilet to prevent the product reaching the wastewater system.

Before dressing or applying a non-airtight bandage, let the gel dry for a few minutes on the skin. If you need to shower or to bathe, apply the product afterwards.

For how long should you use Voltarol Osteoarthritis Joint Pain Relief 1.16% Gel?

Do not use Voltarol Osteoarthritis Joint Pain Relief 1.16% Gel for more than:

- 21 days unless longer treatment is recommended by a doctor.
- For arthritis pain, you may need to apply the gel for up to 7 days (to allow its effect to build up on the joint) before you notice an improvement in your pain.
- If the pain and swelling do not improve within 7 days, or worsen, speak to 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.

Children under 14 years:

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

If you use more Voltarol Osteoarthritis Joint Pain Relief 1.16% Gel 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 or accident and emergency department immediately.

If you forget to use Voltarol Osteoarthritis Joint Pain Relief 1.16% Gel

If you miss your application of Voltarol Osteoarthritis Joint 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 Osteoarthritis Joint 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 Osteoarthritis Joint 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.

Some side effects have unknown frequency (cannot be estimated from available information): local application site irritation, peeling of the skin and skin discolouration.

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 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 Osteoarthritis Joint Pain Relief 1.16% Gel

Keep out of the sight and reach of children.

Do not store above 25 °C. The dispenser is a pressurised container, protect from direct sunlight and do not pierce or burn even when empty.

Do not use Voltarol Osteoarthritis Joint Pain Relief 1.16% Gel after the expiry date stated on the carton and tube, or dispenser.

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 Osteoarthritis Joint Pain Relief 1.16% Gel contains

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

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

What Voltarol Osteoarthritis Joint Pain Relief 1.16% Gel looks like and contents of the pack

Voltarol Osteoarthritis Joint 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 in a pressurised dispenser. This is supplied in a carton and comes in packs of 10g, 30g, 50g, 75ml, 100g, 120g, 150g and 180g (not all pack sizes may be marketed).

Marketing authorisation holder: Haleon UK Trading Limited, The Heights, Weybridge, KT13 0NY, U.K.

Manufacturer: Haleon UK Trading Services Limited, Building 5, First Floor, The Heights, Brooklands, Weybridge, KT13 0NY, United Kingdom

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