

Voltarol

3**Back & Muscle Pain Relief****1.16% Gel****Diclofenac diethylammonium**

• Relieves pain • Reduces inflammation • Cools skin

**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 & 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.

In this leaflet

1. What Voltarol Back & Muscle Pain Relief 1.16% Gel is and what it is used for
2. Before you use Voltarol Back & Muscle Pain Relief 1.16% Gel
3. How to use Voltarol Back & Muscle Pain Relief 1.16% Gel
4. Possible side effects
5. How to store Voltarol Back & Muscle Pain Relief 1.16% Gel
6. Further information

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

Voltarol Back & 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 & 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 & Muscle Pain Relief 1.16% Gel

DO NOT use Voltarol Back & 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 & 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*).

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

Take special care with Voltarol Back & 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.
- 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 Back & 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 & 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 & 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 & 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 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 Back & 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 & 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 & 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.
- Use this medicine only on your skin. Do not use it in your mouth. Inform your doctor immediately in case of accidental swallowing.
- Do not put Voltarol Back & 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.

