PACKAGE LEAFLET: INFORMATION FOR THE USER

Voltarol® Max Strength Pain Relief 2.32% Gel

(diclofenac diethylammonium)

Read all of this leaflet carefully because it contains important information for you.

Always use Voltarol Gel 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.
- This medicine is available without prescription. However, you still need to use Voltarol Gel carefully to get the best results from it. Note that this leaflet is revised on a regular basis with the latest information on your medicine. Please refer to the date at the end of the 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 after 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.

The name of your medicine is Voltarol Max Strength Pain Relief 2.32% Gel but will be referred to as Voltarol Gel throughout this leaflet.

In this leaflet

1. What Voltarol Gel is and what it is used for
2. What you need to know about Voltarol Gel
3. How to use Voltarol Gel
4. Possible side effects
5. How to store Voltarol Gel
6. What is in the pack and further information

1. What Voltarol Gel is and what it is used for

Voltarol 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.

This medicine is used to relieve pain and reduce inflammation and swelling in a number of painful conditions affecting the joints and muscles. Voltarol Gel can be used to treat:
- muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries), relieving pain and helping recovery back to normal function;
- tendonitis (e.g. tennis elbow), swelling around elbow or knee.
- mild arthritis (symptoms of mild arthritis include joint pain at rest, joint pain on movement, joint swelling or stiffness (after sleep or long rest)).

This medicine is intended for use in adults and children aged 14 years and older.

2. What you need to know about Voltarol Gel:

Do not use Voltarol 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.
- 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 pregnancy.

If any of these apply to you, do not use this medicine.

Take special care with Voltarol 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.
- This medicine is only for use on your skin. Do not use it in the mouth. Do not swallow it. Wash your hands after use unless they are the area to be treated. Be careful not to get Voltarol Gel in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.
- 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.
- A brace or wrap commonly used for injuries like sprains can be used, but do not use the gel under airtight (plastic) bandages.
- 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.

If you have any questions, talk to your doctor or pharmacist before using this medicine.

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

Taking other medicines with Voltarol 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 using this medicine.

Voltarol Gel must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

This medicine 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 Gel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, this medicine 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.

Effects of other ingredients
Voltarol Gel contains:

- **propylene glycol,** which may cause a mild localised skin irritation in some people.
- **butylhydroxytoluene,** which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

3. How to use Voltarol 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.

How much Voltarol Gel to use

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

How to apply Voltarol Gel
Do not use if tamper evidence seals are 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 1 penny to a 2 pence piece will usually be sufficient (2-4g). You may notice a slight cooling effect when you rub the gel in. Only use the smallest amount of this medicine needed to relieve your pain but never use more than 8g per day and 56g in one week.

3. After use, if needed, remove remaining amount of the gel from the flip-top cap with cotton towel or absorbent paper until visually 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.

This medicine is for use only on your skin.

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.
How long to use Voltarol Gel for
Do not use this medicine for more than 21 days unless longer treatment is recommended by a doctor.
If the pain and swelling do not improve within 7 days, or if they get worse, tell 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.

If you use more Voltarol 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 immediately.

If you forget to use Voltarol Gel
If you miss your application of this medicine at the correct time, apply it when you remember and 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 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 this medicine 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
(likely to affect between 1 and 10 in every 100 patients)
- Skin rash, itching, reddening or smarting of the skin

Very rare side effects
(likely to affect less than 1 in every 10,000 patients)
- 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 or search for MHRA Yellow Card in the **Google Play** or **Apple App Store.**
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Voltarol Gel

Keep out of the sight and reach of children.
Do not store above 30°C.
Do not use the gel after the expiry date which is stated on the carton and tube labels after 'Exp'. The expiry date refers to the last day of that month.
If the gel becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
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. What is in the pack and further information

What Voltarol Gel contains
The active ingredient in the Voltarol Gel is diclofenac diethylammonium. Each gram gel contains 23.2mg diclofenac diethylammonium.

The other ingredients are: butylhydroxytoluene, carbomers, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, liquid paraffin, macrogol cetostearyl ether, oleyl alcohol, propylene glycol, eucalyptus fragrance composition (with benzyl alcohol, citronellol, coumarin, d-limonene, eugenol, geraniol, linalool) and purified water.

What Voltarol Gel looks like and contents of the pack
Voltarol Gel is white to practically white, cooling, non-greasy, non-staining, soft homogenous, cream-like gel with white triangular screw cap.

It is available in pack size of 100g.

Manufactured by: Haleon Germany GmbH, Barthstrasse 4, 80339 Monachium, Germany.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Voltarol® Max Strength Pain Relief 2.32% Gel; PL 18799/4082

Leaflet date: 02.04.2026 P

Voltarol is the registered trademark of Novartis AG.

Blind or partially sighted?
Is this leaflet hard to see or read?
Call **0208 515 3763** to obtain the leaflet in a format suitable for you.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diclofenac diethylammonium 2.32% w/w Gel

Read all of this leaflet carefully because it contains important information for you.

Always use Diclofenac diethylammonium 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.
- This medicine is available without prescription. However, you still need to use Diclofenac diethylammonium carefully to get the best results from it. Note that this leaflet is revised on a regular basis with the latest information on your medicine. Please refer to the date at the end of the 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 after 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.

The name of your medicine is Diclofenac diethylammonium 2.32% w/w Gel but will be referred to as Diclofenac diethylammonium throughout this leaflet.

In this leaflet

1. What Diclofenac diethylammonium is and what it is used for
2. What you need to know about Diclofenac diethylammonium
3. How to use Diclofenac diethylammonium
4. Possible side effects
5. How to store Diclofenac diethylammonium
6. What is in the pack and further information

1. What Diclofenac diethylammonium is and what it is used for

Diclofenac diethylammonium 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.

This medicine is used to relieve pain and reduce inflammation and swelling in a number of painful conditions affecting the joints and muscles. Diclofenac diethylammonium can be used to treat:
- muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries), relieving pain and helping recovery back to normal function;
- tendonitis (e.g. tennis elbow), swelling around elbow or knee.
- mild arthritis (symptoms of mild arthritis include joint pain at rest, joint pain on movement, joint swelling or stiffness (after sleep or long rest)).

This medicine is intended for use in adults and children aged 14 years and older.

2. What you need to know about Diclofenac diethylammonium:

Do not use Diclofenac diethylammonium 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.
- 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 pregnancy.

If any of these apply to you, do not use this medicine.

Take special care with Diclofenac diethylammonium
- 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.
- This medicine is only for use on your skin. Do not use it in the mouth. Do not swallow it. Wash your hands after use unless they are the area to be treated. Be careful not to get Diclofenac diethylammonium in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.
- 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.
- A brace or wrap commonly used for injuries like sprains can be used, but do not use the gel under airtight (plastic) bandages.
- 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.

If you have any questions, talk to your doctor or pharmacist before using this medicine.

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

Taking other medicines with Diclofenac diethylammonium
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 using this medicine.

Diclofenac diethylammonium must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

This medicine 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.

Diclofenac diethylammonium should only be used under medical advice during breast- feeding as diclofenac passes into breast milk in small amounts. However, this medicine 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.

Effects of other ingredients
Diclofenac diethylammonium contains:
- **propylene glycol,** which may cause a mild localised skin irritation in some people.
- **butylhydroxytoluene,** which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

3. How to use Diclofenac diethylammonium

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.

How much Diclofenac diethylammonium to use

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

How to apply Diclofenac diethylammonium
Do not use if tamper evidence seals are 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 1 penny to a 2 pence piece will usually be sufficient (2-4g). You may notice a slight cooling effect when you rub the gel in. Only use the smallest amount of this medicine needed to relieve your pain but never use more than 8g per day and 56g in one week.

3. After use, if needed, remove remaining amount of the gel from the flip-top cap with cotton
4. towel or absorbent paper until visually 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.

This medicine is for use only on your skin.

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.

How long to use Diclofenac diethylammonium for

Do not use this medicine for more than 21 days unless longer treatment is recommended by a doctor.

If the pain and swelling do not improve within 7 days, or if they get worse, tell 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.

If you use more Diclofenac diethylammonium 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 immediately.

If you forget to use Diclofenac diethylammonium
If you miss your application of this medicine at the correct time, apply it when you remember and 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, Diclofenac diethylammonium 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 this medicine 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).
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(likely to affect between 1 and 10 in every 100 patients)
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Very rare side effects
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Some side effects have unknown frequency
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5. How to store Diclofenac diethylammonium

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Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
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6. What is in the pack and further information

What Diclofenac diethylammonium contains
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Each gram gel contains 23.2mg diclofenac diethylammonium.

The other ingredients are: butylhydroxytoluene, carbomers, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, liquid paraffin, macrogol cetostearyl ether, oleyl alcohol, propylene glycol, eucalyptus fragrance composition (with benzyl alcohol, citronellol, coumarin, d-limonene, eugenol, geraniol, linalool) and purified water.

What Diclofenac diethylammonium looks like and contents of the pack
Diclofenac diethylammonium is white to practically white, cooling, non-greasy, non-staining, soft homogenous, cream-like gel with white triangular screw cap.

It is available in pack size of 100g.

Manufactured by: Haleon Germany GmbH, Barthstrasse 4, 80339 Monachium, Germany.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

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