

Diclac Max Relief 2% w/w gel

diclofenac sodium

ROWEX®

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

1. What Diclac Max Relief gel is and what it is used for
2. What you need to know before you use Diclac Max Relief gel
3. How to use Diclac Max Relief gel
4. Possible side effects
5. How to store Diclac Max Relief gel
6. Contents of the pack and other information

1. What Diclac Max Relief gel is and what it is used for

Diclac Max Relief gel contains the active substance diclofenac diethylamine which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Diclac Max Relief is used in **adults and adolescents aged 14 years and over**: for the treatment of mild to moderate pain associated with muscle and joint injuries, such as sports injuries.

This medicine is intended for short term treatment.

2. What you need to know before you use Diclac Max Relief gel

Do not use Diclac Max Relief gel

- if you are allergic to
 - diclofenac
 - other medicines used to treat pain, fever or inflammation, such as ibuprofen or acetylsalicylic acid (a substance also used to prevent blood clotting) or
 - any of the other ingredients of this medicine (listed in section 6).

Symptoms of an allergic reaction may include: wheezing or shortness of breath (asthma; bronchospasm); skin rash with blisters or hives; swelling of the face, tongue or throat; runny nose.

If you are not sure, ask your doctor or pharmacist.

- if you are in the last 3 months of pregnancy
- in children and adolescents below 14 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before using Diclac Max Relief gel.

You are more likely to have asthma attacks (so-called analgesic intolerance/analgesic asthma), local skin or mucous membrane swelling (so-called quince oedema) or hives than other patients if you suffer from asthma, hay fever, swelling of the nasal membrane (so-called nasal polyps) or chronic obstructive pulmonary disease, chronic respiratory tract infections (particularly associated with hay fever-like symptoms) or hypersensitivity to other painkiller and anti-rheumatic medicines of any kind.

In these patients, Diclac Max Relief gel may only be used under certain precautions (emergency preparedness) and direct medical supervision. The sample applies for patients who are also allergic to other substances e.g. with skin reactions, itching or hives.

When Diclac Max Relief gel is applied to a large area of skin and over a prolonged period, the possibility of systemic side effects from the application of Diclac Max Relief gel cannot be excluded.

Apply Diclac Max Relief gel only to intact, not diseased or injured skin. Avoid contact with eyes and oral mucous membranes. The gel must not be taken orally.

After applying the gel on the skin, you can use a permeable (non-occlusive) bandage but allow the gel to dry on the skin for a few minutes. Do not use an airtight occlusive dressing.

If the symptoms worsen or do not improve after 7 days, consult a doctor.

The use of Diclac Max Relief gel should be discontinued if you develop a skin rash.

Avoid sun exposure, including solarium, when using this medicine.

Prevent children from touching the area to which the gel is applied.

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.

Children and adolescents

Diclac Max Relief gel is contraindicated in children and adolescents under 14 years.

Other medicines and Diclac Max Relief gel

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In intended, cutaneous use of Diclac Max Relief gel no interactions have become known so far.

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.

• Pregnancy

Do not use Diclac Max Relief gel if you are in the last 3 months of pregnancy. You should not use Diclac Max Relief gel during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.

Oral forms (e.g. tablets) of Diclofenac formulation can cause adverse effects in your unborn baby. It is not known if the same risk applies to Diclac Max Relief gel when it is used on the skin.

• Breast-feeding

Diclac Max Relief gel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. Do not apply Diclac Max Relief gel on the breasts if you are a nursing mother nor elsewhere on large areas of skin or for a prolonged period of time.

Driving and using machines

Diclac Max Relief gel has no or negligible influence on the ability to drive or to use machines.

Effects of other ingredients (excipients)

Diclac Max Relief gel contains:

- 50 mg of propylene glycol (E1520) in each gram of the gel, which may cause skin irritation.
- 0.2 mg butylhydroxytoluene (E321) in each gram of the gel, which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.
- up to 0.01 mg hexyl benzoate in each gram of the gel, which may cause local irritation.
- fragrance with citral and eugenol, which may cause allergic reactions. In addition to allergic reactions in sensitised patients, non-sensitised patients may become sensitised.

3. How to use Diclac Max Relief gel

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescent aged 14 years and older

Diclac Max Relief gel is used 2 times a day (preferably morning and evening).

Depending on the size of the affected site to be treated, a cherry to walnut sized quantity, corresponding to 2 - 4 g of gel is required.

The maximum daily dose is 8 g of gel.

Elderly patients

No special dose adjustment is necessary. If you are elderly, you should pay special attention to side effects and, if necessary, consult a doctor or pharmacist.

Impaired kidney or liver function

No dose reduction is necessary.

Use in children and adolescents (under 14 years)

This medicine is contraindicated in children and adolescents under 14 years (see section 2 "Do not use Diclac Max Relief gel").

How to apply

Before using for the first time, remove the plastic seal from the tube. Do not use if the seal is broken.

Diclac Max Relief gel is for cutaneous use only (should only be used on the skin).

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The gel is applied to the affected parts of the body thinly and gently rubbed into the skin. Afterwards, the hands should be wiped with a paper towel and then washed, unless the hands are the area to be treated.

If too much gel is accidentally applied, the excess gel should be wiped with a paper towel.

The paper towel should be disposed of in the household waste to prevent unused product reaching the aquatic environment.

Before applying a bandage, the gel should be left to dry for a few minutes on the skin.

Duration of use
The duration of use depends on the symptoms and the underlying disease.

This medicine should not be used for longer than 7 days without medical advice.

If symptoms worsen or do not improve after 7 days a doctor should be consulted.

If you use more Diclac Max Relief gel than you should
An overdose is unlikely to happen if you use more Diclac Max Relief gel than you should, because the absorption into the blood stream is low when used on the skin. If the recommended dose is significantly exceeded when used on the skin, the gel should be removed and washed off with water.

If you accidentally swallow this medicine, contact your doctor immediately.

If you forget to use Diclac Max Relief gel
If you miss a dose, apply it as soon as possible. Do not use a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine 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 Diclac Max Relief gel and **tell a doctor or pharmacist immediately**:

- Skin rash with blisters; hives (rare: may affect up to 1 in 1 000 people)
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma) (very rare: may affect up to 1 in 10 000 people)
- Swelling of the face, lips, tongue or throat (very rare: may affect up to 1 in 10 000 people).

Other side effects are possible:
Common side effects (may affect up to 1 in 10 people):
Skin rash, itching, reddening, eczema, dermatitis (inflammation of the skin) including contact dermatitis.

Very rare side effects (may affect up to 1 in 10 000 people)
• Pustular rash
• Hypersensitivity reactions (including hives)
• Sensitivity to light with appearance of skin reactions after exposure to sunlight.

When Diclac Max Relief gel is applied to a large area of skin and over a prolonged period, the possibility of systemic side effects (e.g. renal, hepatic or gastrointestinal side effects, systemic hypersensitivity reactions) - as they occur possibly after systemic administration of diclofenac: containing medicines - cannot be completely excluded.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: 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 Diclac Max Relief gel

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Do not refrigerate or freeze.

Do not use this medicine if you notice visible signs of deterioration.

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 Diclac Max Relief gel contains

- The active substance is diclofenac sodium. 1 gram of gel contains diclofenac as 23.2 mg of diclofenac diethylamine, corresponding to 20 mg of diclofenac sodium.
- The other ingredients are: propylene glycol (E1520), oleyl alcohol, isopropyl alcohol, butylhydroxytoluene (E321), diethylamine, paraffin light liquid, macrogol cetostearyl ether, carbomer 980 F, cocoyl caprylocaprate, perfume cream 1876601 (containing hexyl benzoate, citral, eugenol) and purified water.

What Diclac Max Relief gel looks like and contents of the pack
Diclac Max Relief gel is a viscous white gel with a characteristic fragrance with a pH between 6.5 – 8.0.

The gel is packed in an aluminium laminate tube with an HDPE shoulder sealed with a top seal and a polypropylene cap.

Pack sizes: tubes of 50 g, 100 g, 150 g and 180 g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Lek Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.
Kern Pharma S.L., Calle Venus 72, Polígono Industrial Colón II, 08228 Terrassa, (Barcelona), Spain.

This medicine is authorised in the Member States of the European Economic Area under the following names:
AT Diclac 2% - Gel
DK Dilac Forte
EE Diclac
HU Titoplac 20 mg/g gel
ES Diclofenaco Sandoz Care 23,2 mg/g gel
IE Diclac Max Relief 2% w/w gel
IT Sirdalud Antinfiammatorio
NL Diclofenac Sandoz Extra sterk 2,32 %, gel
PT Diclofenac Sandoz Care

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