

PACKAGE LEAFLET: INFORMATION FOR THE USER

DIKLORON 1% Gel **Applied on the skin.**

Active Substance: Each 1 g gel contains 11.6 mg diclofenac diethylammonium equivalent to 10 mg diclofenac sodium.

Excipients: Carbomer 934 P, ethyl alcohol, triethanolamine, methylparaben, deionized water.

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

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you for this medicine.*

In this leaflet:

- 1. What is DIKLORON and what is it used for***
- 2. What you need to know before you use DIKLORON***
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1. WHAT IS DIKLORON AND WHAT IS IT USED FOR

- DIKLORON is a medicine supplied as a clear semisolid gel with alcohol odor containing the active substance diclofenac diethylammonium.
- DIKLORON belongs to a group of medicines called non-steroidal anti-inflammatory preparations used topically. It is only for external use.
- DIKLORON is presented in tubes of 50 g.
- DIKLORON is used in adults for
 - pain, inflammation and swelling due to sprains, strains, bruises or sport injuries,
 - soft tissue inflammation,
 - localized rheumatic diseases

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DIKLORON

Do not use DIKLORON;

- If you have an allergy to diclofenac or to any of the ingredients in DIKLORON (see list of excipients).
- If you 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.
- If you are pregnant (particularly in the last 3 months of your pregnancy)
- Do not apply DIKLORON to skin that has a rash or eczema, cuts or open wounds.

- Do not use in children and adolescents under 14 years of age.

TAKE SPECIAL CARE with DIKLORON

- Use with caution when applying on large areas of skin and over a prolonged period of time.
- DIKLORON gel is for external use only. Do not use in the mouth. Do not swallow it.
- Be careful not to get DIKLORON gel in your eyes. If you get the gel in your eyes, rinse them well with clean water. See your doctor or pharmacist if any discomfort persists.
- During use of DIKLORON; avoid excessive exposure to sunlight.
- Stop the treatment if a skin rash develops.
- DIKLORON can be used with non-occlusive dressings; however, airtight occlusive dressings should not be used.
- Do not use together with other products containing diclofenac.

Please talk to your doctor, even if these warnings were applicable to you at any time in the past.

Using DIKLORON with food and drink

It does not have any interaction with food and drinks due to its route of administration.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

Do not use DIKLORON during pregnancy, especially during the last 3 months of pregnancy.

If you realize that you are pregnant during the treatment contact your doctor or pharmacist immediately.

Breast-Feeding

Consult your doctor or pharmacist before using this medicine.

Do not use DIKLORON during breast-feeding unless clearly necessary. If your doctor sees it necessary, it should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period of time.

Driving and using machines

DIKLORON does not have any effect on your ability to drive or use machines.

Important information about some of the ingredients of DIKLORON

DIKLORON contains methylparaben, which may cause allergic reactions (possibly delayed).

Use of DIKLORON with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO USE DIKLORON

Instructions for proper use and dose/frequency of administration:

Adults:

DIKLORON is applied over the affected area 3 or 4 times daily and rubbed gently into the skin. The amount needed depends on the size of the painful area. For example, 2 to 4 g DIKLORON (an amount ranging from a cherry to a walnut) is sufficient to treat an area of approximately 2-2.5 cm in

diameter.

Do not use DIKLORON for more than 2 weeks for muscle and joint pain (e.g. sprains, strains, bruises) or tendonitis and for more than 3 weeks for arthritis pain, unless recommended by a doctor. You should consult your doctor if the condition (pain and swelling) does not improve within 7 days, or if it gets worse.

Route and method of administration

Gently rub a small amount of gel into the skin around the painful or swollen area. You may feel a slight cooling effect. Wash your hands after application (unless your hands are the site being treated).

Different age groups

Use in children

DIKLORON is not recommended for use in children and adolescents under 14 years of age.

In children aged 14 years and over, it is recommended to consult a doctor if this product is used for more than 7 days for pain relief or if the symptoms worsen.

Use in elderly

The usual adult dosage may be used in elderly.

Special conditions for use

Kidney/Liver Impairment

Dose adjustment is not required.

If you have the impression that the effect of DIKLORON is too strong or too weak, talk to your doctor or pharmacist.

If you use more DIKLORON than you should

If you use too much DIKLORON, talk to your doctor or pharmacist.

If you forget to use DIKLORON

If you forget to use DIKLORON, use it as soon as you remember and use the next on time.

Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects may occur in people with sensitivity to ingredients of DIKLORON.

Stop taking DIKLORON, tell your doctor IMMEDIATELY or go to the nearest hospital emergency department, if you experience any of the following side effects:

- Swelling of the face, lips, tongue or throat (angioedema)
- Skin rash with blisters, hives
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma)

These are all very serious side effects. If you develop any of these, it means that you are seriously allergic to DIKLORON. You may need urgent medical attention or hospitalization.

These very serious side effects are seen very rarely.



Side effects are listed as shown in the following categories:

Very common : may occur in at least 1 in 10 patients.

Common : may occur in less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon : may occur in less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare : may occur in less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

Very rare : may occur in less 1 in 10,000 patients.

Not known : cannot be estimated from the available data.

Tell your doctor straight away or go to the nearest hospital emergency department if you notice any of the following side effects:

Common:

- Skin disease (inflammation, eczema)
- Rash
- Dermatitis (including contact dermatitis)

Rare:

- A skin disease where blisters are formed (bullous dermatitis)

These are all serious side effects. You may need urgent medical attention.

These serious side effects are seen very rarely.

Tell your doctor; if you experience any of the following side effects:

Common:

- Itching
- Redness (erythema)

Very rare:

- Light sensitivity

These are mild side effects of DIKLORON.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DIKLORON

Keep DIKLORON out of the reach and sight of children and in its original container.

Store at room temperature below 25°C. Protect from moisture.

Use in accordance with the expiry date.

Do not use DIKLORON after the expiry date, which is stated on the pack.

Do not use *DIKLORON* if you notice any defect on product and/or its package.



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.

Marketing Authorization Holder:

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