

PACKAGE LEAFLET: INFORMATION FOR THE USER**Diclosal 10 mg/g gel**
Diclofenac sodium

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

Always use this medicine according to the instructions in this leaflet or as directed by your doctor or pharmacist.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve after 7 days.
- If you get any adverse reactions, talk to your doctor or pharmacist. These include any possible adverse reactions not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Diclosal 10 mg/g gel is and what it is used for
2. What you need to know before using Diclosal 10 mg/g gel
3. How to use Diclosal 10 mg/g gel
4. Possible adverse reactions
5. How to store Diclosal 10 mg/g gel
6. Contents of the pack and other information

1. WHAT DICLOSAL 10 mg/g GEL IS AND WHAT IT IS USED FOR

Diclosal 10 mg/g gel contains as active substance diclofenac (as diclofenac sodium) which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is specially formulated to be absorbed into the skin by local massage.

It is used locally to reduce pain, inflammation and edema, in case of painful conditions that affect the muscles and joints.

It can be used in the treatment of the following conditions:

Adults and teenagers aged 14 years and over:

- Muscular or osteoarticular traumas of rheumatic nature (for example, sprains, dislocations, bruises, back pain, sports injuries);
- Minor tendon trauma (tendonitis, such as lateral epicondylitis).

Adults only (18 years of age and older)

- Mild arthritis of the knees or fingers.

If after 7 days you do not feel better or feel worse, you should consult a doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DICLOSAL 10 mg/g GEL

Do not use Diclosal 10 mg/g gel if:

- you are allergic (hypersensitive) to diclofenac sodium, other non-steroidal anti-inflammatory drugs (such as ibuprofen or acetylsalicylic acid) or any of the other ingredients of the medicine (see section 6). Symptoms of an allergic reaction to this medicine may include: wheezing or shortness of breath (asthma), skin rashes with blisters or hives, swelling of the tongue, runny nose;
- you have skin lesions, such as: eczema, infected wounds, burns, open wounds, cuts;
- you had bouts of asthma, urticaria, or allergic rhinitis to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs such as ibuprofen;
- you have gastric or duodenal ulcer;
- you are in the last 3 months of pregnancy;
- you are under 14 years old.

If one of above situations applies to you, do not use Diclosal 10 mg/g gel.

Warnings and precautions

Talk to your doctor or pharmacist before using Diclosal 10 mg/g gel.

- DO NOT apply Diclosal 10 mg/g gel on mucous membranes, especially the eyes. If this happens, rinse your eyes with plenty of water and consult a doctor or a pharmacist;
- DO NOT apply Diclosal 10 mg/g gel on skin lesions, open wounds, cuts, areas of the skin with eczema or hives;
- If a rash appears on the skin after application, discontinue treatment immediately;
- DO NOT apply Diclosal 10 mg/g gel in large areas of skin and for a long time because systemic adverse reactions cannot be excluded, known for oral formulations of diclofenac;
- if you have had or have gastrointestinal bleeding;
- DO NOT use oral non-steroidal anti-inflammatory drugs at the same time (including ibuprofen).

Diclosal 10 mg/g gel is for external use only. Do not use in the oral cavity. Do not swallow.

An orthosis or an elastic bandage can be used in the treatment of sprains, but do not apply Diclosal 10 mg/g gel under occlusive elastic bandage (plastic).

Do not expose yourself to the sun or solarium while using Diclosal 10 mg/g gel.

Ask your doctor or pharmacist for advice before using Diclosal 10 mg/g gel.

Children and teenagers:

Data on the safety and efficacy of administration in children and teenagers under 14 years of age are insufficient (see section *Do not use Diclosal 10 mg/g gel*).

In teenagers 14 years of age and over, if this product is needed for a period of treatment longer than 7 days or if symptoms worsen, the patient / the patient's parents are advised to consult a doctor.

Use of other medicines with Diclosal 10 mg/g gel

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

Concomitant use with other anti-inflammatory drugs, including diclofenac, may increase the risk of adverse reactions.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to be pregnant, ask your doctor or pharmacist for advice before taking this medicine.

In the first 6 months of pregnancy you can use Diclosal 10 mg/g gel only if your doctor recommends it, if it is absolutely necessary and the dose should be kept as low as possible and the duration of treatment as short as possible. Starting with the 6th month of pregnancy, stop using Diclosal 10 mg/g gel because it can harm the foetus or can cause problems at birth.

Diclofenac gel can be absorbed into the blood and passed into breast milk, in the case of women who are breastfeeding a decision should be made whether to stop breastfeeding or stop treatment with Diclosal 10 mg/g gel, given the benefit of breastfeeding for the baby and the benefit of the treatment for the woman.

Diclosal 10 mg/g gel should not be applied on the breast of nursing mothers nor elsewhere on large areas of the skin or for a prolonged period of time.

Driving and using machines

Diclosal 10 mg/g gel has no influence on the ability to drive and use machines.

Important information about some of the ingredients of Diclosal 10 mg/g gel

Diclosal 10 mg/g gel contains propylene glycol.

Propylene glycol (excipient in the medicine composition) may cause local skin irritation in some people.

Diclosal 10 mg/g gel contains methyl p-hydroxybenzoate.

Methyl p-hydroxybenzoate (excipient in the medicine composition) may cause allergic reactions (possibly delayed) in some people.

3. HOW TO USE DICLOSAL 10 mg/g GEL

Always use Diclosal 10 mg/g gel exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and teenagers aged over 14 years

Diclosal 10 mg/g gel is intended for administration to the skin.
Apply Diclosal 10 mg/g gel in the affected area 3- 4 times/ daily.

How to apply Diclosal 10 mg/g gel

1. Before first use, pierce the sealing membrane with the sharp tip of the lid. Diclosal 10 mg/g gel is used by holding the perforated hole of the tube down. Press the base of the tube (where a fold is inscribed with the batch no.) to obtain the required amount of gel.
2. Gently remove a small amount of gel from the tube and apply it on the painful or swollen area. The dose administered to each application varies depending on the surface area affected (quantity ranging as big as a cherry or a walnut).
To achieve gel absorption, perform a gentle and lasting massage of the painful and / or inflamed area. You will feel a slight soothing sensation when you massage the gel to enter the skin.

3. After each application, wash your hands carefully, unless they are the area that is being treated.

How long you can use Diclosal 10 mg/g gel

Use Diclosal 10 mg/g gel, depending on the age group you belong, no more than:

Adults and teenagers 14 years of age and older:

- **14 days** for joint and muscle injuries (e.g. dislocations, stretches, bruises) or tendinitis.

Adults only (18 years of age and older)

- **3 weeks** for pain associated with arthritis.

Long-term treatment may be recommended by a specialist.

If symptoms of pain and inflammation do not improve after 7 days of treatment or get worse, you should see a doctor for a treatment reassessment.

Children and teenagers

Diclosal 10 mg/g gel does not present enough data on safety and efficacy for use in children and teenagers under 14 years of age.

In teenagers 14 years of age and older, if this medicine is needed to treat pain for more than 7 days or if the symptoms worsen, the patient / patient's parents should consult a doctor.

If you use more Diclosal 10 mg/g gel than you should

When administering Diclosal 10 mg/g gel, overdose is unlikely to occur. However, in case of overdose, the surface where the gel was applied should be washed with a large amount of water. In case of accidental ingestion of a quantity of gel, the amount of diclofenac may be sufficient for the occurrence of an overdose (100 g of gel contain 1,000 mg diclofenac sodium); contact your doctor or the emergency department of the nearest hospital.

If you forget to use Diclosal 10 mg/g gel

If you forget to apply a dose of Diclosal 10 mg/g gel at the appointed time, apply another as soon as you remember, and then continue the application as usual. If the time is near the next dose, just apply it. Do not apply a double dose to compensate for the missed dose.

If you stop taking Diclosal 10 mg/g gel

Diclosal 10 mg/g gel is only used when needed. You can stop the treatment as soon as you feel well.

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

4. POSSIBLE ADVERSE REACTIONS

Like all medicines, Diclosal 10 mg/g gel can cause adverse reactions, although not everybody gets them.

Some rare and very rare adverse reactions can be important.

If you have any of the following allergy symptoms, STOP the treatment with Diclosal 10 mg/g gel and ask your doctor or pharmacist.

- Rash on the skin with blisters, hives. These can affect 1 in 10,000 users.
- Wheezing, shortness of breath or tightness in the chest (asthma). These can affect 1 in 10,000 users.
- Swelling of the face, lips, tongue and throat. These can affect 1 in 10,000 users.

Other adverse reactions that may occur are usually mild, transient and harmless (if you are concerned, ask your doctor or pharmacist).

Common adverse reactions (can affect 1 in 10 users): rash, itching, redness or burning of the skin.

Rare adverse reactions (can affect 1 in 1,000 users): bullous dermatitis, allergic manifestations on the skin with localized itching or redness.

Very rare adverse reactions (can affect 1 in 10,000 users): transient rash accompanied by puss blisters, allergic skin reactions, bronchial asthma, especially in patients with allergy to NSAIDs.

The skin can be more sensible to the sun. Possible signs are sunburn with itchiness, swelling and blisters (**do not expose yourself to sunlight while using Diclosal 10 mg/g gel**).

Adverse reactions with unknown frequency (cannot be estimated from the available data): burning sensation at the application site, dry skin.

Other common systemic adverse reactions to NSAIDs (e.g. digestive, renal and hepatic) may occur in cases of increased dermal absorption of the diclofenac sodium in the following situations: large amount of gel applied, wide area of application, the presence of skin lesions, long treatment and use of occlusive dressings.

Reporting of adverse reactions

If you get any adverse reactions, talk to your doctor or pharmacist. These include any possible adverse reaction not listed in this leaflet. You can also report adverse reactions directly via the national reporting system, whose details are published on the web-site of the National Agency for Medicines and Medical devices from Romania <http://www.anm.ro>.

By reporting adverse reactions, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DICLOSAL 10 mg/g GEL

Do not use Diclosal 10 mg/g gel after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

Store below 25°C, in the original package. After first opening, the product should be used within 6 months. Keep this medicine out of the sight and reach of children.

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 to protect the environment.

6. THE CONTENT OF THE PACK AND OTHER INFORMATION

What Diclosal 10 mg/g gel contains

- The active substance is diclofenac sodium. One gram of gel contains 10 mg diclofenac sodium.
- The other ingredients are: carbomer 980, propylene glycol, ethanol 96%, trolamine, methyl parahydroxybenzoate (E 218), purified water.

What Diclosal 10 mg/g gel looks like and content of the pack

Diclosal 10 mg/g gel appears as a homogeneous, transparent, non-aerated, light yellow and with a slight odor of alcohol gel.

It is available in packs with a tube of Al, sealed with aluminium membrane (Al), closed with plastic screw cap (PP= polypropylene), provided with a membrane perforation system. The tube contains 25 g or 45 g gel.

Marketing authorisation holder and manufacturer

Slavia Pharm SRL
44C Theodor Pallady Blvd.,
032266, Bucharest, Romania

This leaflet was revised in April 2022.

Other sources of information

Detailed information on this medicine is available on published on the web-site of the National Agency for Medicines and Medical devices from Romania <http://www.anm.ro>.