

# Clafen 50 mg/gram, gel

## Diclofenac sodium

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Antibiotice



**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 **Clafen** 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 after 5 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:

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### 1. What **Clafen** is and what it is used for

**Clafen** contains as active substance diclofenac sodium, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) with local use. It is used in the local symptomatic treatment in adults for relief of pain and inflammation:

- muscular or osteoarticular of rheumatic origin;
- in case of post-surgical and post-traumatic oedema (for example sprains);
- muscular or osteoarticular of traumatic nature (mild trauma of tendons, muscles, ligaments, etc.).

### 2. Before you use **Clafen**

#### Do not use **Clafen**

- if you are allergic (hypersensitive) to diclofenac sodium, to other non-steroidal anti-inflammatory drugs (NSAIDs), or any of the other ingredients of the medicine;
- if you have cutaneous lesions, such as: moist dermatitis, eczema, infected lesions, burns, wounds;
- if you had attacks of asthma, urticaria, or allergic rhinitis to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs;
- if you are in the last 4 months of pregnancy.

#### Take special care with **Clafen**

- do not use **Clafen** on the mucosae, particularly on the eye

area; do not apply **Clafen** on areas with lesions or wounds of the skin.

- if a skin rash occurs after using diclofenac, discontinue the treatment immediately.
- do not use **Clafen** on large skin areas and over a long period because the occurrence of general side effects, known in case of oral forms of diclofenac, cannot be excluded.
- In case of prolonged use of **Clafen**: you should wear protective gloves when you use the gel.

Do not apply **Clafen** under occlusive dressings.

### Using 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.

Use with other NSAIDs, including diclofenac, may increase the risk of side effects.

### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

During the first 5 months of pregnancy, you can use **Clafen** only on your doctor's recommendation, if it is absolutely necessary. Starting with the 6<sup>th</sup> month of pregnancy, do not use **Clafen**.

### Driving and using machines

**Clafen** has no influence on the ability to drive or use machines.

### Important information about some of the ingredients of **Clafen**

This medicine contains propylene glycol, which may cause skin irritation.

### 3. How to use **Clafen**

**Clafen** should be applied on the skin.

#### Adults

**Clafen** is administered on the affected area, 3 - 4 times a day. The amount of gel administered will vary depending upon the size of the area to be treated, being of approximately 2 to 4 g gel (corresponding to approximately 5 to 10 cm gel).

To facilitate the absorption of the gel, smooth gently the gel on the painful and/or inflamed area.



After each application, wash the hands carefully. Except some strictly recommended cases, in case of soft tissue trauma or abarticular rheumatism, the gel should not be used for more than 14 days and in case of pain due to arthritis for a period exceeding 28 days. If after 5 days of treatment your symptoms worsen or do not improve, you should see your doctor who will review the treatment.

Children and adolescents

Clafen is not recommended for use in children and adolescents, due to the lack of safety and efficacy data.

If you use more Clafen than you should

In case of Clafen administration, overdose is unlikely to occur. However, in this case, the surface on which the gel was applied should be washed with plenty of water. In case of accidental ingestion of a quantity of gel, the amount of diclofenac may be sufficient to show signs of an overdose (for example 100 g gel contain 5,000 mg diclofenac sodium); contact immediately your doctor or the emergency department of the nearest hospital.

If you forget to use Clafen

If you forgot to apply a dose, apply another as soon as you remember. Do not apply a double dose to make up for the one you missed.

If you stop using Clafen

Use Clafen only if necessary. You can stop the treatment immediately after your symptoms improve.

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

4. Possible side effects

Like all medicines, Clafen can cause side effects, although not everybody gets them. Side effects are classified according to the following frequencies:

Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

**Common:** temporary skin eruptions, eczema, redness, dermatitis (including contact dermatitis);  
**Rare:** bullous dermatitis, allergic manifestations on the skin with localized itching or redness;  
**Very rare:** temporary skin eruptions accompanied by blisters with pus, allergic reactions on the skin, attacks of bronchial asthma, especially in patients with allergy to NSAIDs,

swelling of face, tongue, larynx, anaphylactic type reactions, photosensitivity reactions.  
**Other common side effects** to NSAIDs (for example: digestive and renal) may occur in case of increased absorption of diclofenac sodium through the skin, in the following situations: large amount of gel applied, large area of application, presence of lesions on the skin, prolonged period of treatment and use of occlusive dressings. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Clafen

Do not use Clafen after the expiry date stated on the carton after EXP. The expiry date refers to the last day of the month. Store in the original package, at temperatures below 25° C. Keep out of the reach and sight of children.

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. Further information

What Clafen contains

- The active substance is diclofenac sodium. One gram of gel contains 50 mg of diclofenac sodium.
- The other ingredients are: diethylene glycol monoethyl ether, ethanol, propylene glycol, hypromellose, benzyl alcohol, purified water.

What Clafen looks like and contents of the pack

Clafen is a colourless to light pink homogeneous gel.

It is available as outer cartons containing one Al tube of 25 g or 45 g gel.

Marketing Authorisation Holder and Manufacturer  
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