

BIOGESIC 10mg/gram

Diclofenac sodium
Gel

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 Biogesic 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.

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1. What Biogesic is and what it is used for

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

2. Before you use Biogesic

Do not use Biogesic

-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 Biogesic

-do not use Biogesic on the mucosae, particularly on the eye

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

-if a skin rash occurs after using diclofenac, discontinue the treatment immediately.

-do not use Biogesic 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 Biogesic: you should wear protective gloves when you use the gel.

Do not apply Biogesic 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 Biogesic only on your doctor's recommendation, if it is absolutely necessary. Starting with the 6th month of pregnancy, do not use Biogesic.

Driving and using machines

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

Important information about some of the ingredients of Biogesic

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

3. How to use Biogesic

Biogesic should be applied on the skin.

Adults

Biogesic is administered on the affected area, 3 - 4 times a day. The dose administered at each application varies depending on surface of affected area, being of approximately 2 to 4 g gel (corresponding to approximately 5 to 10 cm gel).

To achieve the absorption of the gel, perform a gentle and prolonged massage 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

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

If you use more Biogesic than you should

In case of Biogesic 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 1000 mg diclofenac sodium); contact immediately your doctor or the emergency department of the nearest hospital.

If you forget to use Biogesic

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 Biogesic

Use Biogesic only if is 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, Biogesic can cause side effects, although not everybody gets them.

Side reactions 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 general side effects common 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 Biogesic

Do not use Biogesic 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 Biogesic contains

·The active substance is diclofenac sodium. One gram of gel contains 10 mg of diclofenac sodium.

·The other ingredients are: ethanol 96%, propylene glycol, benzyl alcohol, Carbopol, trolamine, purified water.

What Biogesic looks like and contents of the pack

Biogesic is a colourless homogeneous mass, with a characteristic odour.

It is available as outer cartons containing one Al tube of 40 g gel.

The holder of trademark and Marketing Authorization is
"BioActiveT, United Kingdom."

BioActiveT