

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

(GEBEDICLO GEL) Diclofenac gel BP 1% w/w

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1. WHAT GEBEDICLO GEL IS AND WHAT IT IS USED FOR

- Gebediclo gel is containing 10 mg of diclofenac for each gram of gel.
- Diclofenac is a phenylacetic acid derivative. It leads to inhibition of cyclooxygenase activity, which, then, leads to the inhibition of prostaglandin synthesis and other inflammation mediators. Diclofenac acts as anti-inflammatory and analgesic agent in the treatment of: mild to moderate muscle pains Contusions post-traumatic pain.
- Gebediclo gel is indicated for the treatment of sprains, strains, bruises, soft tissue rheumatism.
- Gebediclo gel is intended to adults and adolescents aged 14 years and over.

2. BEFORE YOU USE GEBEDICLO GEL

Do not use gebediclo gel

- If you are allergic to diclofenac or any of the other ingredients of this medicine (listed in section 6).
- If you are hypersensitive to acetylsalicylic acid or to other non-steroidal anti-inflammatory drugs (NSAIDs), which may arise as asthma, urticaria or other allergic reactions.
- For adults and adolescents under 14 years of age.
- are in the last 3 months of your pregnancy (see also “Pregnancy and breast-feeding”)
- If you have kidney failure.

Take special care with gebediclo gel

- It is important to know that the occurrence of systemic side effects with the topical use of diclofenac is low when compared with the frequency of side effects with the oral use of diclofenac.
- As there is a possibility of Gebediclo gel cutaneous absorption, it is not possible to exclude the occurrence of systemic effects. The risk of the occurrence of these effects depends, among other factors, on the exposed surface, applied quantity and exposure time.
- Cutaneous safety of NSAIDs: It has been reported, very rarely, serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, associated with the administration of NSAIDs. Apparently the risk of occurrence of these reactions is greater at the beginning of treatment, and in most cases these reactions are manifested during the first month of treatment.
- Gebediclo gel should be discontinued at the first signs of rash, mucosal lesions or other manifestations of hypersensitivity.
- Gebediclo gel can only be applied on healthy skin (do not apply on open wounds).

- Gebediclo gel cannot come in contact with conjunctive tissue or mucous membranes (for example in mouth). It cannot be ingested. The area treated with Gebediclo gel should not be exposed to sunlight.

Using other medicines

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

Lithium and Digoxin: Blood levels of lithium and digoxin increased leading to enhanced efficacy and possible toxicity.

Diuretics: Inhibits diuretics but efficacy of potassium sparing diuretics enhanced.

Methotrexate: Toxicity enhanced.

Salicylates: Efficacy of salicylates reduced.

Cyclosporine: Increases nephrotoxicity of both agents.

Hydantoins: Increases serum levels resulting in toxicity.

Concurrent use of aspirin or other NSAIDs may result in an increased incidence of adverse reactions.

Using gebediclo gel with food and drink

There are no known interactions of Gebediclo gel with food and/or drinks.

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 taking this medicine.

Pregnancy

Gebediclo gel must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. Gebediclo gel 1% w/w should only be used under medical advice during the first 6 months of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

Breast-feeding

Gebediclo gel passes into breast milk in small amounts. However, Gebediclo gel 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

Gebediclo gel does not affect the ability to drive or use machines.

Important information about some of the ingredients of gebediclo gel

Gebediclo gel contains propylene Glycol BP, carbora 934P USP-NF, Isopropyl Alcohol BP, and Purified Water BP. which may cause allergic reactions, possibly delayed. Gebediclo gel also contains propylene glycol which during its topic use may cause skin irritation.

3. HOW TO USE GEBEDICLO GEL

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

Adults and adolescents aged 14 years and over Apply thin layers of Gebediclo gel in the affected area, 3 to 4 times daily according to the need of the situation (2-4 g), quantity as big as a cherry or a walnut) and rub gently.

The treatment duration depends on the indications and on the response to the treatment. It is recommended that the treatment should be evaluated 7 days after its start.

In adolescents aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patients/parents of the adolescent is/are advised to consult a doctor.

Gebediclo gel can be used as additional treatment with the oral administration of non-steroidal anti-inflammatory drugs.

Children under the age of 14 years

Gebediclo gel must not be used in children under the age of 14years, since there are no data on the safety and efficacy in this group of patients (see section 2. DO NOT use Gebediclo gel).

Patients with liver or kidney insufficiency

No dosage adjustment is necessary in these patients.

Elderly

The usual adult dosage may be used.

Method of administration

Apply on healthy skin only.

After application, wash your hands, unless these are being treated.

If you use more gebediclo gel than you should

Diclofenac is very poorly absorbed into the bloodstream and thus the overdose with topical use is unlikely. If you or a child accidentally swallows Gebediclo gel contact your doctor, pharmacist or hospital immediately.

If you forget to use gebediclo gel

Do not worry if, occasionally, you forget to apply Gebediclo gel 1%. In these situations, continue with the applications normally, at the usual time.

If you stop using gebediclo gel

The treatment can be stopped at any time, without requiring special care. However, you may feel again pain or swelling in the affected area.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, gebediclo gel can cause side effects, although not everybody gets them.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Commonly found adverse effects with GebeDiclo Gel are dermatitis, local irritation, erythema, photosensitivity, pruritus.

5. HOW TO STORE GEBEDICLO 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 carton and tube.

The expiry date refers to the last day of that month.

Store at a temperature not exceeding 30°C. Protect from light. Do not freeze.

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

After first opening, use the medicinal product for a maximum period of 6 months.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use.

Any unused product or waste material should be disposed of in accordance with local requirements.

These measures will help protect the environment.

6. FURTHER INFORMATION

What gebediclo gel contains

- The active substance is diclofenac sodium.
- The other ingredients are: propylene Glycol BP, carbora 934P USP-NF, Isopropyl Alcohol BP, and Purified Water BP.

What gebediclo gel looks like and contents of the pack Supplier and Manufacturer

Gebediclo gel is a clear, colorless smooth gel filled in 30 gm aluminium collapsible tube. Such 1 printed aluminium collapsible tube is packed in a printed carton with packing insert.

Manufactured by / Fabrqué Par:

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