



Pharmacological information

Composition: Each gram contains:

Diclofenac sodic (equivalent to 12.5 mg of diclofenac diethylammonium)..... 10 mg
Excipients c.b.p

Indications: This medicament is intended for the sintomatic relief of local pain and inflammation. Diclofenac Topical Gel belongs to a kind of therapeutic medicaments known as “Non Steroidal Anti Inflammatory Agents” (NSAIDs). Such are used to relieve the pain and to reduce the inflammation and edema in several painful conditions that affect the articulations and muscles. It is specially formulated to be applied and rubbed into the skin.

Contraindications: Hypersensitivity to Diclofenac or any of the components of this medication, do not use on sunburn, do not administer to patients who have presented allergic reactions (rhinitis, asthma, pruritus, angioedema, urticaria, shock or others), caused by acetylsalicylic acid or other NSAIDs Due to the possibility of crossed hypersensitivity, do not use during the last trimester of pregnancy and in breastfeeding period, do not administer concomitantly with other products containing diclofenac.

Adverse reactions: Although the possibility of systemic adverse effects with topical diclofenac is very small, the following reactions may occur frequently, such as dermatitis (including contact dermatitis), rash, eczema, erythema, and pruritus.

Rare reactions, bullous dermatitis and reactions that may occur very rarely, pustular rash, hypersensitivity (including urticaria), angioedema, asthma, and photosensitivity reaction.

Warnings: It should be used only on intact skin, not on open wounds, mucosa or eczematous skin, avoid contact with the eyes, do not expose the treated area to the sun, do not ingest, do not use with occlusive bandages, do not apply simultaneously in the same area as other topical preparations.

Do not use in large areas. If the symptoms persist for more than 7 days or irritation or worsening occurs, the clinical situation of the patient should be evaluated. Administer with caution in asthmatic patients or with a history of allergic to azo dyes (tartrazine, etc.).

Pharmacological interactions: There have been no reports indicating that Diclofenac Topical Gel interferes with other medicaments.

Dose: The product can be used in adults and adolescents over 14 years.

Adults: Apply a thin layer of the product to the painful area 3 to 4 times a day with a light massage to facilitate penetration. Do not apply more than 7 days in a row.

Overdose: Due to its external use it is not likely that poisoning occurs; In case of accidental ingestion, the symptoms of overdose will depend on the dose ingested and the time elapsed since ingestion. The most frequent manifestations are: nausea, vomiting, abdominal pain and reduced consciousness.

Treatment: if less than one hour has elapsed, perform gastric emptying causing vomiting or gastric lavage. Activated charcoal will be administered in repeated doses and a purgative saline, to favor the non-renal excretion of the drug. Maintenance of vital signs and symptomatic treatment of gastrointestinal irritation will be carried out.

Route of administration: Topical.

Presentations: Topical cream on to 5, 10, 15, 25, 30, 50, 100 and 120 g

Storage conditions:

Keep in a cool and dry place (below 30°C), protect from light.
Medicine, keep out of reach of children.