

DILO®
8% Topical spray

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about DILO

DILO topical spray contains diclofenac sodium 8% with the following excipients: sodium edetate, propylene glycol, ethanol, dimethicone, menthol, hydrochloric acid, and purified water.

DILO is for topical use.

Diclofenac sodium is a non-steroidal anti-inflammatory drug (NSAID) which has also analgesic properties. Diclofenac inhibits the enzyme, cyclooxygenase, an early component of the arachidonic acid cascade.

It is indicated for the local symptomatic relief of mild to moderate pain and inflammation following acute blunt trauma of small and medium-sized joints and periarticular structures.

The way to use DILO

Use according to your doctor's instructions.

The number of actuations depends on the size of the affected area. The recommended dose in adults and children aged 14 years and over is 3 to 4 actuations of DILO topical spray applied 3 times daily. The maximum single dose should not exceed 4 actuations.

The maximum number of actuations is 12 times daily.

- This spray should be massaged gently into the skin.
- Wash your hands afterwards unless they are the site to be treated.
- Wait some minutes to allow drying before covering the skin with clothes or bandages.
- Discontinue the treatment when your symptoms improve.
- This drug should not be used for more than 7 days without consulting your doctor.
- Consult your doctor if no improvement is seen after 3 days or if the symptoms worsen.

In case of overdose

An overdose of this medication is unlikely to occur. If you suspect an overdose, or if the spray solution has been ingested, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Apply the missed dose as soon as you remember unless the next application is near. Go on applying the next scheduled dose as directed. Do not apply a double dose at once.

Contraindications

This drug is contraindicated in the following conditions:

- Hypersensitivity to any of the components, to acetylsalicylic acid or to other NSAID
- During the last trimester of pregnancy
- Application on the breast area of nursing mothers

- Patients with or without chronic asthma in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or other non-steroidal anti-inflammatory agents.
- In the setting of coronary artery bypass graft
- In children less than 14 years of age

Precautions

- This medication is for external use only. It should not be in contact with skin wounds, open injuries, eyes and all mucous membranes. In case of accidental ocular contact, rinse thoroughly with water and inform your doctor.
- This medication should not be used with occlusive dressings.
- Discontinue the treatment if a skin rash occurs after applying the gel.
- Patients should be warned against excessive exposure to sunlight in order to reduce the incidence of photosensitivity.
- Avoid applying on large areas of skin and over a prolonged period of time, unless under medical advice.
- Use caution in patients with a history of, or active, bronchial asthma, allergies, peptic ulceration, patients with renal or hepatic failure, in case of bleeding diathesis or intestinal inflammation, and in patients taking oral NSAIDs.
- Avoid the use of this drug in patients with recent myocardial infarction.
- Consult your doctor before using this medication in case of pregnancy or lactation.

Associations with other medications

Please inform your doctor if you are using any other medication.

Systemic absorption of diclofenac from topical application is very low and therefore interactions are very unlikely.

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

Adverse reactions

Skin disorders are commonly reported and they include: rash, erythema, eczema, dermatitis, and pruritus.

Hypersensitivity reactions, pustular rash, asthma, dermatitis bullous, photosensitivity reaction, have been rarely reported.

Report to your doctor any signs of adverse reactions.

Storage

Store at controlled room temperature (below 30°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

DILO topical spray, diclofenac sodium 8%, bottle of 30 mL

Issue date: 05/2019

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