

DICLOGESIC® GEL

Diclofenac Sodium 1% w/w

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What Diclogesic Gel is used for

Diclogesic Gel is used for the external treatment of pain, inflammation and swelling in:

- Injuries of tendons, ligaments, muscles and joints, e.g. sprains, bruises, strains, or back pain after sport or accidents.
- Localized forms of soft tissue rheumatism such as tendinitis (tennis elbow), shoulder-hand syndrome, bursitis, periarthropathies and for the symptomatic treatment of osteoarthritis of small and medium- sized joints located close to the skin such as the finger joints or knee joints.

How Diclogesic Gel works

Diclogesic Gel contains the active ingredient diclofenac, which belongs to a group of medicines called non-steroidal anti-rheumatic drugs (analgesic and anti-inflammatory medicines).

Diclogesic gel has analgesic and anti-inflammatory properties and has a

soothing and cooling effect due to the aqueous-alcoholic base.

Before you use Diclogesic Gel

- When you must not use it

Diclogesic Gel should not be used in cases of hypersensitivity to the active substance diclofenac or other analgesic and anti-inflammatory agents (especially acetylsalicylic acid /aspirin and ibuprofen) and in case of hypersensitivity to propylene glycol, isopropyl alcohol or other excipients. Such hypersensitivity is expressed for example by asthma, respiratory problems, skin rash, urticarial, swelling of the face and tongue, rhinorrhea (runny nose).

Diclogesic Gel should not be used during the 3rd trimester of pregnancy.

- Before you start to use it

Diclogesic Gel should not be applied on open wounds (e.g. abrasions, cuts) or on damaged skin (e.g. eczema, skin rash). Diclogesic Gel should not be used for long periods over large areas except on medical prescription. Avoid contact with eyes and mucous membranes.

In case of contact, rinse thoroughly with water. Inform your doctor in case of persisting problems. Do not swallow the product. If accidentally swallow the Gel or if a child does, contact your doctor immediately.

Some patients may develop minor, localized skin irritation due to propylene glycol contained in Diclogesic Gel.

- Taking other medicines

Diclogesic Gel should not be used with hermetic bandages. Inform your doctor or pharmacist if you have had allergic reactions after the use of similar products (antirheumatic ointments). If you

have another illness, you are allergic, you are taking or are already using other medicines for internal or external usage (including self medication).

Pregnancy and breast feeding:

During the 1st and 2nd trimester of pregnancy and during breastfeeding, Diclogesic Gel should not be used because it can harm the unborn child or cause problems at birth.

As a precaution, you should avoid, if possible, to take medication during pregnancy and breast-feeding, or consult your doctor or your pharmacist advice..

How to use Diclogesic Gel

To remove the seal before first use, unscrew and remove the cap. Use the reverse side of the cap to insert, twist and remove the seal from the tube.

- How much to use

Adult and children from 12 years:

Depend on the size of the painful or swollen area or surfaces to be treated, rub in with light massage, or with more pronounced massage in case of muscular pain, an amount of 2-4g of Diclogesic Gel (cherry walnut size amount) 3-4 times a day. Wash hands after application, except for the treatment of finger arthritis.

Children under 12 years:

Up to now, the use and safety of diclogesic gel in children below the age of 12 has not been systematically tested and is not recommended. Follow the dosage indicated on the package leaflet or prescribed by your doctor. If you think that the effect of the drug is too weak or too strong contact your doctor or pharmacist.

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Inform your doctor if the symptoms worsen or if the symptoms have not improved after one week.

- When to use it

Diclogesic Gel is used when there is pain, inflammation and swelling in :

- Injuries of tendons, ligaments, muscles and joints, e.g. sprains, bruises, strains, or back pain after sport or accidents.
- Localized forms of soft tissue rheumatism such as tendinitis (tennis elbow), shoulder-hand syndrome, bursitis, periarthropathies and for the symptomatic treatment of osteoarthritis of small and medium- sized joints located close to the skin such as the finger joints or knee joints.

- How long to use it

Diclogesic Gel should not be used longer than 2 weeks without medical prescription.

- If you forget to use it

If you miss a treatment with Diclogesic Gel, apply the treatment as soon as possible and then go on with the normal treatment. Do not apply double amount at once to make up the forgotten treatment.

- If you use too much (overdose)

Contact your doctor or pharmacist

While you are using it

- Things you must not do

Diclogesic Gel should not be applied on open wounds (e.g. abrasions, cuts) or damaged skin (e.g. eczema, skin rash).

- Things to be careful of

Diclogesic Gel should not be used in cases of hypersensitivity to the active substance diclofenac or other

analgesic and anti-inflammatory agents (especially acetylsalicylic acid /aspirin and ibuprofen) and in case of hypersensitivity to propylene glycol, isopropyl alcohol or other excipients.

Side effects

The use of Diclogesic Gel can cause the following side effects: in rare to very rare cases, side effects may be quite severe.

If any of the following side effects occur, stop immediately the treatment with Diclogesic Gel and inform your doctor.

- severe skin rash with blisters, urticarial;
- wheezing, shortness of breath, asthma;
- swelling of the face, lips, tongue and throat.

The following other side effects are usually mild and transient:

- skin rash, itching, redness and skin burning;
- In very rare cases, an increased sensitivity to sunlight can occur. The symptoms of such skin sensitization are itchy sunburn, swelling and blistering.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Diclogesic Gel

- Storage

Store in a dry place below 25°C
Keep medicament out of reach of children.

- Disposal

Discard unused content 6 months after cap seal is broken

Do not use Diclogesic Gel after expiry date which is stated on the box. The expiry date refers to the last day of the month.

Medicine should not be disposed of via wastewater or household waste.

Product Description

- What it looks like

Diclogesic Gel is white to off-white opaque gel

- Ingredients

- Active ingredient(s)

The active ingredient is diclofenac sodium (as diclofenac diethylamine) 1% (w/w)

- Inactive ingredients

Carbomer, Isopropyl alcohol, propylene glycol, macrogol cetostearyl ether, paraffin liquid, cocoyl capryocaprinate, fragrance, diethylamine, purified water.

- MAL number:

MAL19971301AZ

Manufacturer

Dar Al Dawa Development & Investment Co. Ltd.
P.O. Box 9364,
Amman, 11191,
Jordan.

Product Registration Holder

Antah Pharma Sdn. Bhd.
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Date of revision

13 April 2022

Serial Number :

NPRA(R2/1)190528/158