

DICLOTROY (Diclofenac Diethylamine)

Topical Solution 4.64% w/v)

Diclofenac Diethylamine (46.40mg)

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What Diclotroy is used for

Diclotroy is used to relieve pain and swelling in a number of painful conditions such as low back pain or pain following sprain, strain and blunt trauma to tendons, ligaments, muscles and joints.

How Diclotroy works

Diclotroy contains the active substance diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs. It acts by inhibiting the prostaglandin synthesis responsible for pain.

Before you use Diclotroy

- When you must not use it

Do not use Diclotroy:

- If you are allergic (hypersensitive) to diclofenac or other medicine used to relieve pain and inflammation such as ibuprofen or acetylsalicylic acid.
- In the last trimester of pregnancy
- If you are below 14 years of age

- Before you start use it

Tell your pharmacist or doctor if you are using any other painkillers.

Pregnancy

You must tell your doctor if you are pregnant, think you may be pregnant or plan to get pregnant. Do not use Diclotroy if you are pregnant especially during the last 3 months of pregnancy as it could harm unborn child or cause problems at delivery.

Diclotroy should be used with caution and only if clearly necessary during the first 6 months of pregnancy.

Lactation

Tell your doctor if you are breast-feeding or about to start breast-feeding. Do not use it if you are breast-feeding. Ask your doctor, health-care provider or pharmacist for advice before taking any medicine.

- Taking other medicines

Please tell a doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription, before you use Diclotroy. In particular, you should tell your doctor if you are taking the following:

- Tablets, capsules or suppositories for pain including any containing diclofenac sodium, aspirin or any other anti-inflammatory agent for example ibuprofen.

How to use Diclotroy

Diclotroy is for external use only and not to be administered orally. It should not be applied on any mucosa (moist tissue that lines certain parts of the inside of your body eg. mouth, nose), open wound, cut or diseased skin.

Ensure that the site of application is clean and dry before applying Diclotroy. Before using Diclotroy for the first time, prime the pump by spraying it into air 2-3 times.

- How much to use

Adults

On the affected area, apply 4 pump strokes (0.4ml equivalent to 16mg of diclofenac sodium) 4 times a day at regular intervals. Number of the pump strokes to be applied may be higher or lower depending on the area to be treated. The maximum single dose of 7 pump strokes and the maximum daily dose of 30 pump strokes (120 mg of diclofenac sodium) should not be exceeded.

- It should be sprayed from a distance of 6-8 inches from the site of application.
- Diclotroy is a non-aqueous (non-water-based) solution, hence the spray pattern will not be like the spray pattern of aqueous solutions or aerosol sprays.
- The prime purpose of the spray system is to ensure accurate dosing with each metered dose spray, which delivers 0.1 ml of solution.
- After applying the required number of sprays, spread the solution gently with your fingertip.
- Do not massage the treated area after application.
- Avoid wearing clothing over the Diclotroy treated area until the treated area is dry.
- It is recommended that lowest effective dose for shortest duration should be used.
- Discontinue treatment when the symptoms (pain and/or swelling) have subsided.
- Consult your doctor, if the pain and/or swelling do not improve or if they get worse within 7 days.
- When it is required for more than 7 days, use as per recommended by your doctor.

Children

Use in children is not recommended.

Elderly

Care should be taken when using DICLOTROY in the elderly and your doctor may also monitor your kidney conditions.

- When to use it

Always use Diclotroy exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- How long to use it

Consult with your doctor or pharmacist for the treatment period.

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- If you forget to use it

Use the spray as soon as possible you remember but do not apply more than recommended. Do not use double dose to make up the forgotten dose.

- If you use too much (overdose)

If you use more sprays, then you should wipe the excess amount of solution with the cloth or tissue. If you or child accidentally swallows the solution, inform your doctor immediately or go to the nearest hospital with the bottle and leaflet.

While you are using it

- Things you must do

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking Diclotroy.

- Things you must not do

- Do not apply to skin with conditions such as cuts, open wound, or on skin that has rash or eczema.
- Diclotroy is for external use only. do not use it in the mouth. Do not swallow it. Be careful not to get solution in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.
- Do not cover the treated area with occlusive bandages (waterproof or non-breathable) or plasters.
- Do not sunbathe or use sun lamps whilst using this medicine.

- Things to be careful of

Discontinue use if irritation or sensitivity reaction develops.

Side effects

Like all medicines, Diclotroy can cause side effects although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

- Skin rash with blisters
- Hives
- Wheezing
- Shortness of breath
- Feeling of tightness in the chest
- Swelling of the face, lips, tongue or throat
- Skin rash, itching
- Sunburn with itching, 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 Diclotroy

- Storage

Store below 30°C. Keep out of reach of children. Keep the bottle in upright position.

- Disposal

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.

Product Description

- What it looks like

Diclotroy is a clear, colorless to yellow coloured solution filled in 30 ml glass bottles with metered dose spray.

- Ingredients

- Active ingredient
Diclofenac Diethylamine eq to
Diclofenac Sodium BP

- Inactive ingredients

Absolute alcohol (ethanol), Butylated Hydroxy Anisole, Butylated Hydroxy Toluene, Oleic Acid, Menthol, Glycerol, Propylene Glycol.

- MAL number(s):

Manufacturer

Troikaa Pharmaceuticals Ltd
Virochannagar- 382 170, Gujarat, India

Product Registration Holder

Unimed Sdn Bhd
53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara,
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Date of revision

12/01/2023

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