

# UNIREN Gel 1% w/w

Diclofenac diethylammonium (1%w/w)

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## What UNIREN Gel is used for

Treatment of:

- Localized forms of soft-tissue rheumatism (Disturbance caused by muscle, joint, tendon or bone pain), e.g. tendovaginitis (inflammation of the tendon and its sheath), shoulder-hand syndrome (pain and stiffness in shoulder and arm), bursitis (inflammation of the bursa), periarthropathy (inflammation of the tissues around a joint.).
- Localized rheumatic (disease affecting joints) disease, e.g. osteoarthritis (degenerative joint disease) of the spine and peripheral joints;
- Inflammation of the tendons, ligaments, muscles, and joints, e.g. due to sprains, strains, or bruises after trauma.

## How UNIREN Gel works

UNIREN gel contains a substance called Diclofenac. It belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs).

The mechanism by which Diclofenac affects actinic keratosis (rough, scaly patch on skin) is unknown. Like other nonsteroidal anti-inflammatory drugs (NSAIDs), Diclofenac inhibits the actions of prostaglandins (a chemical in your body).

## Before you use UNIREN Gel

### -When you must not use it

- Do not use UNIREN gel:
  - If you are allergic or hypersensitive to Diclofenac or any of the other ingredients listed at the end of this leaflet

- If you have experienced hypersensitivity reactions such as symptoms of asthma, allergic rhinitis (Inflammation of the nasal mucous membrane) or urticaria (itching or hives), to Aspirin (medication used to reduce fever, reduce pain and prevent blood clot) or other non-steroidal anti-inflammatory drugs (NSAIDs)

Do not use this medicine if any of the above condition applies to you. If you are not sure, get advice from your doctor or pharmacist before taking UNIREN Gel.

### -Before you start to use it

Tell your doctor if you have or have had any of the following conditions:

- Ulceration, bleeding and perforation of the stomach and intestines.
- Dyspepsia (discomfort at the epigastric region due to digestion problems).
- Heart disease
- Hypertension (high blood pressure)
- Elderly
- Smoking
- Drink alcohol

UNIREN gel may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin blisters and skin peeling. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Please consult your doctor before start to use UNIREN gel if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking UNIREN gel against the benefits they expect it will have for you.

### -Taking other medicines

Please inform your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that you buy without prescription and herbal medicines.

Tell your doctor or pharmacist if you are using other non-steroidal anti-inflammatory drug (NSAID) or other products containing Diclofenac.

## How to use UNIREN Gel

### -How much to use

Topical

Depending on the size of the painful area to be treated, 2 – 4 grams of UNIREN Gel (cherry to walnut sized amount) should be applied 3 – 4 times daily to the affected sites and gently rubbed in.

### -When to use it

Use as directed by your doctor or pharmacist.

### -How long to use it

Continue applying UNIREN gel for as long as your doctor recommends. You will need to see your doctor to review your treatment after 14 days.

### -If you forget to use it

If you miss a dose, apply the next dose as soon as you remember, provided that you do not apply more than the recommended dose in 24 hours. Do not apply if it is almost time for your next dose.

Do not double the amount applied than needed.

### -If you use too much (Overdose)

An overdose of topical Diclofenac gel is extremely unlikely due to the low systemic absorption. Oral ingestion of topical Diclofenac sodium gel results in significant systemic side effects. In case you accidentally take too much, contact your doctor immediately or your nearest hospital for specific procedure and treatment.

## While you are using it

### -Things you must do

Apply your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are applying UNIREN gel.

UNIREN gel should be applied only to intact, non-diseased skin.

### -Things you must not do

Do not apply to skin wounds or open injuries.

UNIREN gel should not be used with occlusion.

Do not allow UNIREN gel to come into contact with your eyes or mucous

membrane, and should never be taken by mouth.

-Things to be careful of

Avoid the following due to possible photosensitivity reactions may happen:

- direct sunlight exposure
- use of sunlamp
- use of tanning bed or tanning booth

**Side effects**

UNIREN Gel is usually well tolerated. Like all medicines, UNIREN gel can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if you experience any of the following and they worry you:

Local reactions:

Allergic or non-allergic contact dermatitis (symptoms and signs such as itching, reddening, edema, papules, vesicles, bullae or scaling skin).

Systemic reactions:

Generalized skin rash, hypersensitivity reactions e.g. asthmatic attacks, angioedema (swelling around the eyes and lips and sometimes of the genitals, hands, and feet), and photosensitivity reactions.

General:

Systemic absorption of UNIREN Gel is low compared with oral dosage forms of Diclofenac and the likelihood of systemic effects occurring with topical Diclofenac is small compared with the frequency of side effects associated with oral Diclofenac.

However, where UNIREN Gel is applied to a relatively large area of skin and over a prolonged period, the possibility of systemic side effects cannot be completely excluded. Please consult your doctor if you are suffering from asthma disease.

If any of the side effects happens, or if you notice any undesirable effects which have not been mentioned here, discontinue using this medication and consult your doctor / pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring by calling Tel: 03-78835550, or visiting the website

[portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

**Storage and Disposal of UNIREN Gel**

-Storage

Store at temperature of not more than 30°C. Keep out of the reach and sight of children.

-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

Colorless, transparent, smooth, homogenous gel with characteristic odor.

-Ingredients

Active ingredient:

Diclofenac diethylammonium

Inactive ingredients:

Methylparaben, Menthol, Peppermint oil, Butylated hydroxytoluene, Isopropyl alcohol, Propylene glycol, Carbomer 940, Trolamine, Purified water

-MAL number

MAL07082849A

**Manufacturer**

UNISON LABORATORIES CO., LTD.

39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao, Chachoengsao 24000 Thailand

**Product Registration Holder**

MEDISPEC (M) SDN.BHD

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