# **UNIREN Spray 1% w/w**

Diclofenac diethylammonium eq. to Diclofenac sodium (1% w/w)

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# What UNIREN Spray is used for

UNIREN Spray is used to relieve the pain and swelling affecting small or mediumsized joints, muscles and surrounding tissues.

# How UNIREN Spray works

UNIREN Spray contains the active substance Diclofenac sodium, which belongs to a group of non-steroidal antiinflammatory drugs (NSAID).

# Before you use UNIREN Spray

# When you must not use it

- If you are allergic to Diclofenac or other ingredients of UNIREN Spray
- If you have ever had an allergic reaction to acetylsalicylic acid or any other NSAID
- Please see section on 'Pregnancy and breast-feeding'.
- If you are below 14 years of age

#### Pregnancy and breast-feeding

This medicine should not be used by women who are pregnant or breastfeeding.

Consult your doctor for further information if you are pregnant or breast-feeding.

# Before you start to use it

Take special care with UNIREN Spray:

- If you have or have had stomach ulcers.
- If you have ever suffered from asthma or any other allergies
- Do not use in eyes, nose or mouth and on open wounds or infected skin areas.
- Never swallow UNIREN Spray
- Do not cover the treated area with airtight or waterproof bandages or plasters.

# Taking other medicine

Please tell your doctor or pharmacist:

• if you are taking or have recently taken any other medicines, including

medicines obtained without a prescription.

• If you are taking tablets, capsules or suppositories for pain including any containing Diclofenac, Aspirin or any other anti-inflammatory agent.

Speak to your doctor or pharmacist before you use UNIREN Spray.

# How to use UNIREN Spray

How much to use

Topical

For adults and adolescents aged 14 years and over

- UNIREN Spray should be sprayed onto the skin.
- UNIREN Spray should be applied 3-4 times a day.

UNIREN Spray is for external use only. It must only be used on unbroken skin. It is important to use UNIREN Spray correctly. Follow the instructions carefully:

- Wash your hands after usage unless they are the site being treated.
- A period of at least 4 hours should be left between applications. The spray should not be applied more than 4 times in a 24 hour period.
- If there is no improvement in your symptoms after 7 days, talk to a doctor.
- If the symptoms improve but not completely disappear, do not continue using for more than 7 days without consulting a doctor.

#### When to use it

Always use UNIREN Spray as described above. You should check with your doctor or pharmacist if you are not sure.

#### How long to use it

When the pain and swelling disappear stop using the medicine.

#### If you forget to use it

- Use the spray as soon as you remember, but do not apply more than the recommended dose. Then carry on as before.
- Do not use a double dose to make up for a forgotten dose.

# If you use too much (Overdose)

- If you use more of your medicine than you should wipe the surplus UNIREN Spray with a tissue.
- If you swallow some of the spray, inform your doctor immediately or go to the nearest hospital casualty department. Take the bottle and this leaflet with you.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

# While you are using it

#### <u>Things you must do</u>

Use your medicine exactly as your doctor has told you.

Tell the doctor, dentist and pharmacist treating you that you are using the product.

Tell your doctor immediately if you become pregnant while using this medication.

# Things you must not do

- Do not consume UNIREN spray solution. It is for external use only.
- Do not use on open wounds or broken skin.
- Do not take any new medicines without consulting your doctor or pharmacist.

# Things to be careful of

Ask your doctor or pharmacist for advice before taking any medicine.

*Effects on ability to drive and use machines* 

UNIREN Spray is unlikely to make you feel dizzy or drowsy.

If it does make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

# Side effects

Like all medicines, UNIREN Spray can cause side effects, although not everybody gets them.

Discontinue use of UNIREN Spray if any skin rash develops or if you have an allergy to its ingredients. Following the use of other topical Diclofenac preparations, reactions at the site of application have been reported commonly. These include rashes, itching reddening, burning sensations or scaling of the skin.

If topical NSAIDs are applied to large areas of the skin continuously for a long period of time, other side effects may occur. In rare cases, aggravated asthma, various skin disorders, stomach pain, and gastric may occur. This may be due to previous history of asthma or allergic diseases.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website <u>npra.gov.my</u> [Consumers  $\rightarrow$ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

# Storage and disposal of UNIREN Spray

<u>Storage</u>

Store at temperature of not more than  $30^{\circ}$ C.

# <u>Disposal</u>

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?

Clear, pale yellow solution with mentholcamphor fragrance. It is supplied in 60 mL bottle.

# Ingredients

-The active ingredient is: Each 100g of spray solution contains Diclofenac diethylammonium eq. to Diclofenac sodium 1 g (1% w/w)

-Other ingredients are: Propylene glycol, Menthol, Camphor, Anise oil, Eucalyptus oil, Peppermint oil, Ketone 1650B, Butylated Hydroxytoluene, Isopropyl alcohol, Ethyl alcohol 95% and Purified water

MAL. NO: MAL16015071AZ

# <u>Manufacturer</u>

UNISON LABORATORIES CO., LTD. 39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao, Chachoengsao 24000 Thailand

# Product Registration Holder

Medispec (M) Sdn Bhd B-1-07, Jalan SS 25/22, Taman Mayang, 47301 Petaling Jaya, Selangor, Malaysia.

# Date of Revision

12/06/2023