

## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

### TRANGEL

(Diclofenac Diethylamine Gel 1% w/w)

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription.

However, you still need to use Trangel carefully to get the best results from it.

- Keep this leaflet, you may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve within 7 days.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Trangel is and what it is used for
2. Before you use Trangel
3. How to use Trangel
4. Possible side effects
5. How to store Trangel
6. Further information

#### **1. What Trangel is and what it is used for**

Trangel contains the active substance diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is specially formulated for rubbing into the skin and is used to relieve pain and reduce inflammation and swelling in painful conditions affecting the joints and muscles.

Trangel can be used to treat: - muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries) - tendonitis (e.g. tennis elbow) - mild arthritis (symptoms of mild arthritis include joint pain at rest, joint pain on movement, joint swelling or stiffness (after sleep or long rest)).

#### **2. Before you use Trangel**

##### **Do not use Trangel if you:**

- have an allergy (hypersensitivity) to any of the ingredients in the product
- have ever had an allergic reaction to diclofenac or other medicines used to treat pain, fever or inflammation, such as aspirin or ibuprofen. Symptoms of an allergic reaction to these medicines may include: asthma, wheezing or shortness of breath; skin rash or hives; swelling of the face or tongue; runny nose.

- are using any other medicine containing diclofenac or are taking oral NSAIDs such as aspirin or ibuprofen.
- have severe joint pain of recent onset that is not related to an injury or period of overuse.
- feel ill, have a temperature or any other symptoms that accompany the pain.
- are in the last 3 months of your pregnancy (see also pregnancy and breast-feeding section).

This medicine is not recommended for use in children under 14 years of age.

### **Take special care with Trangel**

- Do not apply the gel to skin that has (i) a rash or eczema (ii) cuts or open wounds. Stop the treatment if a skin rash develops after applying the product.
- Avoid applying on large areas of skin and over a prolonged period of time, unless under medical advice.
- Be careful when sunbathing or using sun lamps as your skin may be more sensitive to sunlight.
- If you have a stomach or duodenal ulcer (or a history of), tell your doctor or pharmacist before using the gel.
- If you have or have ever had asthma speak to your doctor or pharmacist before using the gel.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including those obtained without a prescription. Do not use Trangel if you are already taking diclofenac tablets or other NSAID pain/inflammation tablets (e.g. aspirin or ibuprofen).

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Trangel must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. Trangel should only be used under medical advice during the first 6 months of pregnancy and the dose should be kept as low and duration of treatment as short as possible. Trangel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Trangel should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period of time. Consult your doctor or pharmacist for further information if you are pregnant or breastfeeding.

### **Driving and using machines**

Trangel, when used as directed, is not expected to have any effect on your ability to drive or use machines.

### **Important information about some of the ingredients of Trangel**

The gel formulation contains propylene glycol which may cause mild localised skin irritation in some people.

### **3. How to use Trangel**

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

#### **Adults and adolescents 14 years and over:**

##### **Before using for the first time, open as follows:**

- laminated tube: Unscrew cap and remove. Reverse the cap, engage with the nozzle, twist and remove the plastic seal from the tube. Do not use if seal is broken.

##### **How to apply:**

Gently squeeze out a small amount of gel from the tube and apply to the painful or swollen area, slowly rubbing into the skin.

##### **When and how much to use:**

- Apply 3 to 4 times a day. Allow at least 4 hours between applications of the gel. Do not apply more than 4 times in any 24 hour period.
- The amount needed will vary depending on the size of the painful or swollen area; an amount ranging in size from 2 to 4g will usually be sufficient.
- You may notice a slight cooling effect when you rub the gel in.
- Only use the smallest amount of Trangel needed to relieve your pain but never use more than 16g per day and 112g in one week.

##### **How and where to use:**

- You can apply the gel to a maximum of 2 joints (such as your knees or elbows). If you need to apply it to more than 2 joints, consult your doctor.
- Do not rub the gel into cuts, open wounds or any other area where the skin is abnormal. After rubbing the gel into the skin, do not cover with bandages or sticking plaster.
- The gel is for external use only. Do not use it in your mouth.
- Be careful not to get the gel in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.
- Wash your hands after rubbing in Trangel, unless your hands are the site being treated.

##### **For how long should you use Trangel?**

##### **Do not use Trangel for more than:**

- 14 days unless longer treatment is recommended by a doctor.
- For arthritis pain, you may need to apply the gel for up to 7 days (to allow its effect to build up on the joint) before you notice an improvement in your pain.
- If the pain and swelling do not improve within 7 days, or worsen, speak to your doctor. - In children aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

##### **Children under 14 years:**

This medicine is not recommended for use in children under 14 years of age.

**If you use more Trangel than you should**

If you or a child accidentally swallows Trangel, contact your doctor or accident and emergency department immediately.

**If you forget to use Trangel**

If you miss your application of Trangel at the correct time, apply it as soon as you remember then carry on as normal.

Do not apply a double quantity to make up for a forgotten application.

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

**4. Possible side effects**

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

**Some rare and very rare side effects might be serious**

If you experience any of the following signs of allergy, STOP using Trangel and tell a doctor or pharmacist immediately:

Skin rash with blisters; hives (may affect between 1 and 10 in every 10,000 people).

Wheezing, shortness of breath or feeling of tightness in the chest (asthma) (may affect less than 1 in every 10,000 people).

Swelling of the face, lips, tongue or throat (may affect less than 1 in every 10,000 people).

**Other side effects which may occur are**

usually mild, passing and harmless (if you are concerned, tell a doctor or pharmacist).

**Common side effects (may affect between 1 and 10 in every 100 people)**

Skin rash, itching, reddening or smarting of the skin

**Very rare side effects (may affect less than 1 in every 10,000 people)**

the skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering.

**Some side effects have unknown frequency (cannot be estimated from available information):**

local application site irritation, skin discolouration.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse.

**5. How to store Trangel**

Keep out of the sight and reach of children.

Do not store above 30°C.

Store in the original package.

Do not use Trangel after the expiry date stated on the carton and tube.

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.

## **6. Further information**

### **What Trangel contains**

Each g gel contains 1.16 % w/w diclofenac diethylammonium, equivalent to 1.0 % w/w of diclofenac sodium.

**Also contains the following inactive ingredients:** Carbopol 934, Triethanolamine, Essences Cologne 530, Sodium Methyl Paraben, Sodium Propyl Paraben, Isopropyl Propylene glycol and Purified water.

### **What Trangel looks like and contents of the pack**

Trangel is a smooth transparent gel, with slight odour of cologne free from any foreign particles, filled in 20 gm aluminium collapsible tubes.

Made in India by :

**NEM LABORATORIES PRIVATE LTD.,**

133, Krishna Indl. Estate,

Navghar, Vasai Road (E),

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