

**PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**  
**(LEORUB) Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate, Menthol Gel 30 gram**

**In this leaflet:**

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**1. WHAT NAME LEORUB IS AND WHAT IT IS USED FOR**

Leorub is contain diclofenac diethylamine, linseed oil, methyl salicylate, menthol gel. Which act as non-steroidal anti-inflammatory (NSAID) and analgesic preparation designed for external application in Diclofenac is of the group of nonsteroidal. Anti-inflammatory drugs, It inhibits cyclooxygenase, suppresses biosynthesis of prostaglandins endogenous substances, which play a significant role in the genesis of the inflammation, pain and fever, Diclofenac reduces pain, eliminates inflammation. Menthol acts on cold receptors, It constricts capillaries and decreases their permeability, gives sensation of coolness, Menthol provides local revulsive and moderate anelgesic actons, Methyl salicylate is a derivative of salicylic acid, which has local irritant action, Methyl salicylate causes formation a great number of biologically active substances and their output into blood because of Irritation of skin receptors. There is a release of P substance from neurons. Decrease of P substance in nerve endings cause decrease of pain sensation. In addition Methyl salicylate as one of the group of nonsteroidal anti-inflammatory drugs inhibits synthesis of prostaglandins because of cyclooxygenase inhibition that decreases swelling and infiltration of inflamed tissues. Linseed oil, major component of which is alfa-linolenic acid (ether of unsaturated fatty acid) has anti-inflammatory effect, antioxidant properties, improves blood circulation at the place of application.

Leorub has action after applied topically act as fast relief from low back pain, muscular aches and joint pain.

It is used in the treatment of back pain, knee pain, sprain and strains, ankle sprain, wrist sprain, soft tissue disorders, osteoarthritis knee, spondylosis, cervical spondylosis, arthritis, shoulder lesions, frozen shoulder, prolapsed intervertebral disc, thumb, knee, shoulder stiffness, rheumatoid arthritis and tennis elbow.

**2. BEFORE YOU USE LEORUB**

**Do not use leorub**

- if you are contraindicated in individuals with a known history of allergic (hypersensitive) to diclofenac diethylamine, linseed oil, methyl salicylate, menthol or any of the other ingredients of Leorub. It is contraindicated in patients with or without chronic asthma in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory agents (NSAIDs).

### **Take special care with leorub**

#### **Special warnings and precautions**

- Leorub should be applied only to intact, non-diseased skin and not to skin wounds or open injuries.
- It is necessary to wash hands after usage of leorub to avoid the accidental entry of drug in eyes and mucous tunics.
- Do not apply a double dose. Leo Rub is for external use only.  
Topical use only

#### **Using other medicines**

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Avoid using other topical medications containing nonsteroidal anti-inflammatory drugs, on the affected area.

#### **Using Leorub with food and drink**

None

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

Ask your doctor, health care provider or pharmacist for advice before taking any medicine. Safety of Leo Rub in human pregnancy and lactation has not been established Leorub is not recommended for use during pregnancy and lactation.

#### **Driving and using machines**

None.

#### **Important information about some of the ingredients of {product name}**

Discontinue use if excessive irritation occurs. Or as directed by Physician,

### **3. HOW TO USE LEORUB**

Always use leorub exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure. The usual dose is gently massage Leo Rub into the affected area until penetration of the gel is complete.

Apply 2-3 times daily.

Not to be Use on children.

Discontinue use if excessive irritation occurs. Or as directed by Physician.

#### **If you use more leorub than you should**

Leorub can cause side effects (see section 4).

#### **If you forget to take leorub**

Do not take a double dose to make up for a forgotten dose.

### **If you stop using leorub**

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

## **4. POSSIBLE SIDE EFFECTS**

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist. Generally, LeoRub gel is well tolerated, Commonly found adverse effects, with LeoRub are skin rash, oedema and appearance of wheals, papules, scutes, reddening skin itch or prickling may occur in the site of application, The more uncommon adverse effects with LeoRub are oedema of face (angioedema), apnoea and photosensitivity.

## **5. HOW TO STORE LEORUB**

Keep out of the reach and sight of children.

Store at a temperature not exceeding 30°C. Protect from light. Do not freeze.

Do not use leorub after the expiry date which is stated on the label, carton, and tube after abbreviation used for expiry date. The expiry date refers to the last day of that month.

Do not use leorub if you notice description of the visible signs of deterioration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What leorub contains**

- The active substance(s) are Diclofenac Diethylamine BP + Linseed Oil BP + Methyl Salicylate BP + Menthol BP.
- The other ingredient (s) are sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate, Isopropyl Alcohol, Butylated Hydroxyanisole, Polysorbate 80 (Tween -80), Propylene Glycol, Carbomer 934 P (Acrypol 934-P ), Triethanolamine, Essence Fancy Floral SK 1251, Butylated Hydroxytoluene, Propyl Gallate, Sodium Bisulphite, Isopropyl Myristate, Disodium Edetate, Purified Water.

### **What leorub looks like and contents of the pack Supplier and Manufacturer**

White colour smooth gel filled in 30 gm in aluminium collapsible tube. Such 1 printed aluminium collapsible tube is packed in a printed carton with packing insert.

**Manufactured by / Fabrqué Par:**

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