

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
(SEDIMOL ROLLON GEL) Diclofenac Diethylamine, Linseed Oil, Menthol with Methyl Salicylate. (Diclofenac Diethylamine BP Eq to Diclofenac Sodium + Linseed Oil BP + Methyl Salicylate BP + Menthol BP)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

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

1. WHAT NAME SEDIMOL ROLLON GEL IS AND WHAT IT IS USED FOR

Sedimol Rollon Gel 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 analgesic actions, 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.

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

It is used in the treatment local treatment of localized forms of soft tissue rheumatism, e.g. tendovaginitis, shoulder-hand syndrome and bursitis and periarthropathy; localized

rheumatic diseases, e.g. osteoarthritis of the spine and peripheral joints; post-traumatic inflammation of the ligaments, tendons, muscles and joints due to trauma, e.g. due to sprains, strains and bruises.

2. BEFORE YOU USE SEDIMOL ROLLON GEL

Do not use Sedimol Rollon Gel

- 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 Sedimol Gel. 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 Sedimol Rollon Gel

Special warnings and precautions

- Sedimol Rollon Gel 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 Sedimol Rollon Gel to avoid the accidental entry of drug in eyes and mucous tunics.
- Do not apply a double dose. Sedimol Rollon Gel 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 Sedimol Rollon Gel 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 Sedimol Rollon Gel in human pregnancy and lactation has not been established. Sedimol Rollon Gel is not recommended for use during pregnancy and lactation.

Driving and using machines

None.

Important information about some of the ingredients of Sedimol Rollon Gel

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

3. HOW TO USE SEDIMOL ROLLON GEL

Always use Sedimol Rollon Gel 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 Sedimol Rollon Gel into the affected area until penetration of the gel is complete. Depending on the size of the painful area to be treated, 2-4 g Sedimol Rollon Gel (cherry to walnut-sized amount, which is enough for an area of about 400-800 cm²).

Apply 3-4 times daily to the affected sites and gently rubbed-in.

The duration of treatment depends on the indication and the patient's response. It is advisable to review the treatment after 2 weeks. Sedimol Rollon Gel can also be used as an assistant with other dosage forms of Diclofenac.

Not to be Use on children.

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

If you use more Sedimol Rollon Gel than you should

Sedimol Rollon Gel can cause side effects (see section 4).

If you forget to take Sedimol Rollon Gel

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

If you stop using Sedimol Rollon Gel

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, Sedimol Rollon Gel 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, Sedimol Rollon Gel is well tolerated, Commonly found adverse effects, with Sedimol Rollon Gel are skin rash, oedema and appearance of wheals, papules, scutes, Reddening or smarting of the skin, Itching or prickling may occur in the site of application, The more uncommon adverse effects with Sedimol Rollon Gel are oedema of face (angioedema), apnoea and photosensitivity.

5. HOW TO STORE SEDIMOL GEL

Keep out of the reach and sight of children.

Store at below 30°C. Protect from light. Do not freeze.

Do not use Sedimol Rollon Gel 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 Sedimol Rollon Gel 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 Sedimol Rollon Gel contains

- The active substance(s) are Diclofenac Diethylamine BP + Linseed Oil BP + Methyl Salicylate BP + Menthol BP. Gel Base QS.
- 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 Sedimol Rollon Gel looks like and contents of the pack Supplier and Manufacturer

White colour smooth Gel filled in white plastic roll-on container with sky blue cap having socket, blue coloured socket cover and plastic ball for roll on, such 12 container is packed in Inner carton with package insert.

Manufactured by / Fabrqué Par:

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