

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

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

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

Sedimol 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 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 GEL

Do not use Sedimol 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 Gel

Special warnings and precautions

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

Driving and using machines

None.

Important information about some of the ingredients of Sedimol Gel

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

3. HOW TO USE SEDIMOL GEL

Always use Sedimol 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 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 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 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 Gel than you should

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

If you forget to take Sedimol Gel

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

If you stop using Sedimol 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 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 gel is well tolerated, Commonly found adverse effects, with Sedimol 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 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 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 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 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 934P (Acrypol 934-P), Triethanolamine, Essence Fancy Floral SK1251, Butylated Hydroxytoluene, Propyl Gallate, Sodium Bisulphite, Isopropyl Myristate, Disodium Edetate, Purified Water.

What Sedimol Gel 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:

Lincoln Pharmaceuticals Limited

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