1.3.3.2 English Leaflet

CLOFEN
Creamagel
Percutaneous Anti-inflammatory Agent

Composition
Each 100 grams of Clofen Creamagel contains:
Active ingredient: Diclofenac diethylamine equivalent to diclofenac sodium 1 gram.
Excipients: Carbopol, isopropyl alcohol, propylene glycol, liquid paraffin, capric acid ester, cetomacrogol, diethylamine, lavender oil, rose oil and purified water.

Properties
Clofen Creamagel is an anti-inflammatory and analgesic preparation intended for external use.
The active substance of Clofen Creamagel, diclofenac diethylamine, is a non-steroidal anti-inflammatory agent, and it is supplied in a novel dosage form which, when applied to the skin, ensures excellent penetration and accumulation of the active component in the underlying tissue. The first response is a soothing and cooling effect, followed by relief from both acute and chronic inflammatory reactions.
In the presence of inflammation of traumatic or rheumatic origin, Clofen Creamagel elicits a clinical response characterised by a marked decrease in inflammatory swelling. Clofen Creamagel also provides an effective relief from tenderness and pain on movement.

Indications
Clofen Creamagel is effective in the local treatment of:
- Traumatic inflammation of the tendons, ligaments, muscles and joints e.g. due to sprains, strains and bruises.
- Localized forms of soft-tissue rheumatism, e.g. tendovaginitis, shoulder-hand syndrome and bursitis.
- Localized rheumatic diseases, e.g. osteoarthrosis of peripheral joints and of the vertebral column and periarthropathy.

Dosage and Administration
Depending on the size of the painful site to be treated, an adequate amount (2 - 4 gm) of Clofen Creamagel is applied to the affected parts and rubbed in gently 3 - 4 times daily.

Clofen Creamagel may also be used as accompanying treatment together with other dosage forms of Clofen.

Contraindications
Hypersensitivity to diclofenac sodium or any other non-steroidal anti-inflammatory agent is a contraindication.

Warning
Elevations of one or more liver function tests may occur during treatment with diclofenac. Diclofenac should be stopped if these tests show abnormalities that persist or worsen, or if liver disease develops.
Drug-induced hepatotoxicity has been reported in the first month but can occur at any time during treatment with diclofenac. Rare cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with or without jaundice, and liver failure have been reported. Some of these cases resulted in fatalities or liver transplantation.
Transaminases should be measured periodically in patients receiving long-term therapy with diclofenac. The optimum times for making the first and subsequent transaminase
measurement are not known. Based on clinical trial data and postmarketing experiences, transaminases should be monitored within 4 to 8 weeks after initiating treatment with diclofenac.

**Precautions**

*Clofen Creamagel* should not be applied to broken skin injuries, but rather only to intact skin surfaces. Contact with the eyes or with mucous membranes should be avoided. Hands should be washed after use.

*Clofen Creamagel* should not be used with occlusive dressing.

*Clofen Creamagel* is not recommended for use by pregnant women.

**Side Effects**

*Clofen Creamagel* is usually well tolerated. Occasionally, itching, reddening, smarting of the skin or outbreak of a skin rash may occur.

Photosensitivity reactions have been reported in isolated cases.

Systemic side effects due to diclofenac sodium might occur when *Clofen Creamagel* is applied into large areas and over a prolonged period.

**Presentation**

*Clofen Creamagel*: Tubes of 20 or 50 gm.

* Store at a temperature of 15 - 25ºC.

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**THIS IS A MEDICAMENT**

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of the children.

Below is the logo of Council of Arab Health Ministers, Union of Arab Pharmacists:

Any information? Call Toll Free No. (971) 800-4994

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