Summary of Product Characteristics

1. Name of the medicinal Product

Diclofenac gel BP 1% w/w

2. Qualitative and Quantitative Composition

Qualitative declaration

Diclofenac Diethylamine BP

Quantitative declaration

Each tube contains 10.0% of Propylene Glycol.
For full list of Excipients, see section 6.1.

3. Pharmaceutical Form

Gel
Distribution category POM
A clear colourless smooth gel

4. Clinical Particulars

1. Therapeutic Indications

It is used to relieve pain and reduce swelling in a number of painful conditions affecting the joints and muscles. It relieves rheumatic and muscular pain, and reduces swelling and inflammation, e.g., in injuries involving the tendons, ligaments, muscles and joints. For the relief of sprains, strains or bruises, backache, tendinitis (e.g., tennis elbow), and for localized and mild arthritis.

2. ***Posology and Method of Administration***

Adults and Adolescents over 12 years of age: Depending on the size of the painful area to be treated, 2-4 g (a circular shaped mass approximately 2.0-2.5cm in diameter) Diclofenac Gel should be applied 3-4 times daily to the affected sites and gently rubbed-in. Duration of treatment depend on the indication and the patient's response. It is advisable to review the treatment after 2 weeks.

3. Contraindications

Hypersensitivity to Diclofenac, acetylsalicylic acid, isopropanol propylene glycol or other components of the gel base.
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).
The use in children and adolescents aged less than 14 years is contraindicated.

4. Special warnings and precautions for use

Diclofenac Gel should be applied only to intact skin and or open wounds. It should not come into contact with the eyes or mucous membranes.
Pregnancy: Since no experience has been acquired with Diclofenac Gel in pregnancy or lactation, it is not recommended for use in these circumstances.
During the last trimester of pregnancy, the use of prostaglandin synthetase inhibitors may result in premature closure of the ductus arteriosus, or in uterine inertia.
Animal data has shown an increased incidence of dystonia and delayed parturition when drug administration is continued into late pregnancy.
Lactation: It is not known whether topical diclofenac is excreted in human milk, and Diclofenac Gel is therefore not recommended during breast-feeding, if there are compelling

reasons for using Diclofenac Gel during breast feeding it should not be applied to the breast or to large areas of skin, nor should it be used for a prolonged period.

Caution for use: excipients with known effect: Propylene glycol: If you suffer from a liver or kidney disease and same effects as drinking alcohol and increase the likelihood of side effects. Do not take this medicine unless recommended by your physician. Your physician may carry out extra checks while you are taking this medicine.

5. Interaction with other medicinal products and other forms of interaction

Systemic absorption of Diclofenac Gel is low and hence the risks of interactions are less. No drugs interactions have been reported with Diclofenac Gel to date.

6. Pregnancy and Lactation

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7. ***Effects on ability to Drive and use Machines***

Effects on ability to drive and use machine is not known

8. Undesirable effect

Occasional skin rash, itching and redness of the skin.

9. Overdose

There has been no experience of overdose with Diclofenac gel.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Pharmacotherapeutic Group: Non-steroidal anti-inflammatory & Analgesic

ATC Code: M02AA15

When Diclofenac Gel is applied locally, the active substances are absorbed through the skin, determined by reference to the urinary excretion of Diclofenac and its hydroxylated metabolites. After topical administration of Diclofenac Gel to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid.

5.2 Pharmacokinetic Properties

When Diclofenac Gel is applied locally, the active substances are absorbed through the skin, determined by reference to the urinary excretion of Diclofenac and its hydroxylated metabolites. After topical administration of Diclofenac Gel to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid.

5.3 Preclinical Safety Data

Not Applicable.

6. Pharmaceutical Particulars

6.1 List of Excipients

Propylene Glycol BP
Carbomer 934P (Acrypol 934-P) USP-NF
Isopropyl Alcohol BP
Triethanolamine BP
Purified Water BP

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

36 Months

6.4 Special Precautions for Storage

Do not store above 30°C. Protect from light.

6.5 Nature and contents of container

Clear, colorless smooth gel filled in 30 gm Aluminum Collapsible Tube. Such 1 tube is packed in a printed carton with a packing insert.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses

7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

7.2 Name and Address of Manufacturing Site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

8 Marketing Authorization Number

TAN 22 HM 0005

9 Date of First <Registration> / Renewal of The <Registration>

10/01/2022

10 Date of Revision of the Text