1.6.1 Name of the Medicinal Product

Diclofenac Gel BP

1.6.1.1 Product Name

Diclofenac Gel BP

1.6.1.2 Strength

Diclofenac Diethylamine BP 1.16 % w/w

Eq. to diclofenac sodium 1.00 % w/w

1.6.1.3 Pharmaceutical Dosage Form

Topical Gel

1.6.2 Quality and Quantitative Composition

1.6.2.1 Qualitative Declaration

Diclofenac Diethylamine Eq. to Diclofenac Sodium

1.6.2.2 Quantitative Declaration

Sr. No.	Ingredients Chemical Name	Specification	Standard Quantity(%w/w)	Reason for Inclusion
01	Diclofenac Diethylamine Eq. to Diclofenac Sodium	BP 2015	1.16 eq. to 1.00	Non-steroidal Anti-inflammatory & Analgesic
02	Propylene Glycol	BP 2015	10.0	Solvent
03	Carbomer 934P	USP38-NF33	1.33	Viscosity increasing agent
04	Isopropyl Alcohol	BP 2015	5.00	Cosolvent/Emollient

Sr. No.	Ingredients Chemical Name	Specification	Standard Quantity(%w/w)	Reason for Inclusion
05	Triethanolamine	BP 2015	2.70	Alkalizing Agent
06	Purified Water	BP 2015	Q.S.	Vehicle

1.6.3 Pharmaceutical Form

Topical Gel

Clear, colorless smooth gel filled in Aluminum Collapsible Tube.

1.6.4 Clinical Particulars

1.6.4.1 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.

1.6.4.2 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.

1.6.4.3 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.

1.6.4.4 Special warning 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.

1.6.4.5 Interaction with other medicinal products and other forms of interactions

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.

1.6.4.6 Pregnancy and lactation

Pregnancy

Since no experience has been acquired with Vivian 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 Vivian is therefore not recommended during breast-feeding, if there are compelling reasons for using Vivian 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.

1.6.4.7 Effects on ability to drive and use machine

None known.

1.6.4.8 Undesirable effects

Occasional skin rash, itching and redness of the skin.

1.6.4.9 Overdose

There has been no experience of overdose with Diclofenac gel.

1.6.5 Pharmacological Properties

1.6.5.1 Pharmacodynamic Properties

Diclofenac is a non-steroidal anti-inflammatory (NSAID) and analgesic preparation designed for external application. Diclofenac is a potent non-steroidal anti-inflammatory drug with analgesic and antipyretic properties. It is also has some uricosuric effect. Diclofenac inhibits cyclo-oxygenase activity with a reduction of production of prostaglandins in the tissue.

1.6.5.2 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.

1.6.5.3 Preclinical safety Data

Not Applicable

1.6.6 Pharmaceutical Particulars

1.6.6.1 List of excipients

Propylene Glycol
Carbomer 934P
Isopropyl Alcohol
Triethanolamine
Purified Water

1.6.6.2 Incompatibilities

Not applicable.

1.6.6.3 Shelf life

36 months

1.6.6.4 Special precautions for storage

Store below 30°C. Protect from light.

1.6.6.5 Nature and contents of container

Clear, colourless smooth gel filled in 15 gm Aluminum Collapsible Tube. Such 1 tube is packed in a printed carton with a packing insert.

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

1.6.7 Marketing Authorization Holder

Name : **LINCOLN PHARMACEUTICALS LTD.**

Address : Trimul Estate, Khatraj, Tal. Kalol,
Dist. Gandhinagar,
Gujarat, India.

Phone : +91-2764-665000

Fax : +91-2764-281809

E-mail : info@lincolnpharma.com

Website : www.lincolnpharma.com

1.6.8 Marketing Authorization Numbers

To be included after obtaining first registration.

1.6.9 Date of first authorization/renewal of the authorization

To be included after obtaining first registration.

1.6.10 Date of revision of the text
