

Name of the medicinal Product

NORBAFLEX (Diclofenac Diethylamine, Linseed Oil, Menthol with Methyl Salicylate Gel)

Qualitative and Quantitative Composition

Qualitative declaration

Diclofenac Diethylamine BP

Linseed Oil BP

Menthol USP

Methyl Salicylate BP

Quantitative declaration

Sr. No.	Ingredients	Specifications	Standard Quantity/ (% w/w)	Reason for Inclusion
01	Diclofenac Diethylamine Eq. to Diclofenac Sodium	BP	1.16 % Eq. to 1.00 %	Analgesic, Anti-inflammatory
02	Methyl Salicylate	BP	10.00	Counter Irritant
03	Menthol	USP	5.00	Counter Irritant
04	Linseed Oil	BP	3.00	Emollient
05	Sodium Methyl Hydroxy benzoate	BP	0.15	Preservative
06	Sodium Propyl Hydroxy benzoate	BP	0.03	Preservative
07	Isopropyl Alcohol	BP	6.00	Solvent
08	Butylated Hydroxyanisole	BP	0.05	Antioxidant
09	Polysorbate-80 (Tween-80)	BP	3.00	Wetting agent
10	Propylene Glycol	BP	5.00	Solvent
11	Carbomer 934P (Acrypol 934-P)	USP-NF	0.80	Gel base

12	Triethanolamine	BP	0.20	Alkalizing agent
14	Butylated Hydroxytoluene	BP	0.10	Antioxidant
15	Propyl Gallate	BP	0.05	Antioxidant
16	Sodium Bisulphite	IHS	0.20	Antioxidant
17	Isopropyl Myristate	BP	2.00	Emollient
18	Disodium Edetate	BP	0.05	Chelating agent
19	Benzyl Alcohol	BP	10.0	Preservative
19	Purified Water	BP	Q.S.	Vehicle

Pharmaceutical Form

Topical Ointment

Clinical Particulars

Therapeutic Indications

Local treatment of localised forms of soft tissue rheumatism, e.g. tendovaginitis, shoulder-hand syndrome and bursitis and periarthropathy; localised 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.

Posology and Method of Administration

Depending on the size of the painful area to be treated, 2-4 g Diclofenac Gel (cherry to walnut-sized amount, which is enough for an area of about 400-800 cm²) should be applied 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. Diclofenac Gel can also be used as an adjunct with other dosage forms of Diclofenac.

Contraindications

Hypersensitivity to Diclofenac, acetylsalicylic acid and other nonsteroidal anti-inflammatory agents, as well as to isopropanol or propylene glycol.

Special Warnings and Special Precautions for Use

Diclofenac Gel should be applied only to intact skin and not to broken skin or open wounds. It should not come into contact with the eyes or mucous membranes.

Interaction with other medicinal products and other forms of interaction

When you use Diclofenac gel on the skin, it is especially important to have knowledge of following : Medicine for inflammation and pain (non-narcotic), including aspirin the risk of the serious side effects may be increased.

If patient have any other medical problems, especially :

Stomach or Intestinal ulcers or bleeding : Diclofenac may make these conditions worse.

Kidney diseases or liver diseases : Effect of this medicine may be increased because of slower removal of the medicine from the body.

Fertility, Pregnancy and Lactation

Pregnancy: No data available

Lactation: No data available

Effects on ability To Drive and use Machines

No studies on the effects on the ability to drive and use machines have been performed.

Undesirable effects

Occasional skin rash, itching, reddening or smarting of the skin.

Overdose

There has been no experience of overdose with gel.

Pharmacological Properties

Pharmacodynamics Properties

Diclofenac is an anti-inflammatory and analgesic preparation designed for external application. Diclofenac is a potent non-steroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic properties. It also has some uricosuric effect. Diclofenac inhibits cyclo-oxygenase activity with a reduction in the tissue production of prostaglandins such as PgF₂ and PgE₂. The anti-inflammatory effect, measured in the adjuvant-induced arthritis model, is greater than that of aspirin and similar to Indometacin. With regard to its analgesic effect, diclofenac is not a narcotic.

Pharmacokinetic Properties

When Diclofenac gel is applied locally, the active substance is absorbed through the skin, determined by reference to the urinary excretion of diclofenac and its hydroxylated metabolites. In patients with rheumatoid arthritis who had received repeated treatment with Diclofenac Gel, the concentrations measured in the region of the inflamed wrist, both in the synovial fluid and in the synovial tissue removed during surgery, proved to be higher than the plasma concentrations.

Preclinical Safety Data

Not Known

Pharmaceutical Particulars

List of Excipients

Sodium Methyl Hydroxybenzoate BP

Sodium Propyl Hydroxybenzoate BP

Isopropyl Alcohol BP

Butylated Hydroxyanisole BP



Polysorbate-80 (Tween-80) BP
Propylene Glycol BP
Carbomer 934P (Acrypol 934-P) USP-NF
Triethanolamine BP
Butylated Hydroxytoluene BP
Propyl Gallate BP
Sodium Bisulphite
Isopropyl Myristate BP
Disodium Edetate BP
Purified Water BP

Incompatibilities

Not applicable.

Shelf Life

24 months

Special Precautions for Storage

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

Nature and Contents of Container

Gel filled in 40gm Plastic roll on container such a container packed in carton with package insert.

Special precaution for disposal and other handling

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



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

--

Date of Revision of the Text

Dosimetry (If Applicable)

Not Applicable

Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable

Product name & Emboss



NORBAFLEX[®] GEL
 Diclofenac Diethylamine,
 Diclofenac Sodium & Methyl Salicylate

NORBAFLEX[®] GEL
 Diclofenac Diethylamine, Diclofenac Sodium,
 Methyl Salicylate & Virgin Linseed Oil

30g

NORBAFLEX[®] GEL
 Diclofenac Diethylamine, Diclofenac Sodium,
 Methyl Salicylate & Virgin Linseed Oil

For External Use Only
 Avoid contact with eyes
 Do not exceed prescribed dosage
 Read package insert before use.
DOSAGE:
 As directed by physician.
 Keep out of reach of children.

COMPOSITION:
 Diclofenac Diethylamine BP 1.16%w/w
 Diclofenac sodium BP 1%w/w
 Methyl Salicylate BP 10% w/w
 Virgin Linseed oil BP 3%w/w
 Menthol USP 5%w/w
 Store below 30°C in a dry place.
 Protect from sunlight. Keep out of reach of children.

30g

NORBAFLEX[®] GEL
 Diclofenac Diethylamine,
 Diclofenac Sodium & Methyl Salicylate

Batch No:
Mfg. Date:
Exp. Date:
NAFDAC REG. NO.

Manufactured by:
Marine Life Sciences Ltd.
 Plot No.30, Phase - III (Ext.), HPSIDC,
 Baddi -Distt.Solan (H.P.), India.

Distributed in Nigeria by:
NORBARC
 PHARMACEUTICAL LIMITED
 7, Adekunle Street, Badagry, Lagos