SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

1.1 Brand Name	:	**Adiflam Gel**
1.2 Generic Name	:	Diclofenac Gel BP 1.00% w/w
1.3 Strength	:	Diclofenac Diethylamine 1.16% w/w (eq. to Diclofenac Sodium 1.00% w/w)
1.4 Pharmaceutical Form	:	Gel

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Diclofenac Diethylamine	BP	1.16 % w/w
eq. to Diclofenac Sodium	BP	1.00 % w/w
Washable base		q.s.

3. PHARMACEUTICAL FORM

Gel

White coloured opaque gel having characteristic odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adiflam Gel is indicated for the temporary relief of minor aches and pains of muscles and joints due to muscle strains, sprains and bruises or overexertion, as an adjunct in the management of minor stiffness or sourness associated with arthritis, rheumatism, lumbago, fibrositis, sciatica and stiff neck.

4.2 Posology and method of administration

Mode of application: Puncture the nozzle seal. Apply to the affected areas 2-3 times daily according to the need of the situation or as per the direction of the physician. Rub Gel gently into affected areas until it disappears.

4.3 Contraindications

Adiflam Gel is contraindicated in patients with hypersensitivity to the active substance or any of the excipients used in the formulations. The use in children and adolescents aged less than 14 years is contraindicated.

4.4 Special warnings and special precautions for use

FOR EXTERNAL USE ONLY. Not for veterinary use. Topical Diclofenac should be applied only to intact non-diseased skin, and not to skin wounds or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes and should not be ingested. Diclofenac 1% Gel should be discontinued at the first signs of rash, mucosal injuries or other hypersensitivity manifestations.

4.5 Interaction with other FPPs and Other forms of Interaction

ACE Inhibitors: Increased risk of renal impairment when NSAIDs are given with ACE inhibitors, also hypotensive effect antagonized.

Adrenergic Neurone Blockers: NSAIDs antagonise the hypotensive effect of adrenergic neurone blockers.

Beta-Blockers: NSAIDs antagonise the hypotensive effect of Beta-blocker.

Cardiac Glycosides: NSAIDs possibly increase the plasma concentration of cardiac glycosides, also possible exacerbation of heart failure and reduction of renal function.
Diuretics: The risk of nephrotoxicity of NSAID increased by diuretics.

Since systemic absorption of Diclofenac from a topical application is very low such interactions are very unlikely to occur.

4.6 Pregnancy and lactation

Pregnancy: The systemic concentration of Diclofenac is lower after topical administration, compared to oral formulations. During the first and second trimesters of pregnancy, Diclofenac should not be given unless necessary. Diclofenac is contraindicated during the third trimester of pregnancy.

Lactation: Like other NSAIDs, Diclofenac passes into breast milk in small amounts. NSAIDs should not be applied to the breasts of nursing mothers.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Immune system disorder: Very rare- Hypersensitivity (including urticaria), angioneurotic oedema. **Infections and infestations: Very rare-** Rash pustular. **Skin and subcutaneous tissue disorders: Common-** Rash, eczema, erythema, dermatitis (including dermatitis contact), pruritus; **Rare-** Dermatitis bullous; **Very rare-** Photosensitivity reaction; **Not known-** Burning sensation at the application site, Dry skin.

Adverse Reactions: Dermatitis, local irritation, erythema, photosensitivity & pruritus.

4.9 Overdose & Treatment

In an accidental ingestion of Diclofenac gel, symptomatic treatment should be provided as per the direction of the physician. The low systemic absorption of topical Diclofenac renders overdoses very unlikely.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analgesic & Anti- inflammatory.

Mechanism of action:

Diclofenac is a phenylacetic acid derivative. It leads to the inhibition of cyclooxygenase activity, which then leads to the inhibition of the synthesis of prostaglandin and other mediators of inflammation. It acts as a percutaneous anti-inflammatory and analgesic agent in the treatment of topical symptoms of rheumatic and non-rheumatic pains of the locomotor apparatus.

5.2 Pharmacokinetic properties

Absorption: After topical application, Diclofenac is well-absorbed into the subcutaneous layers of the skin. **Distribution:** The Diclofenac concentration was measured on plasma and tissue and synovial fluid after topical administration in the hands and knees joints. The maximum plasma concentration of Diclofenac applied topically was about 100 times lower than after oral administration. **Metabolism:** Biotransformation of Diclofenac takes place partly by glucuronidation of the intact molecule, but mainly by single and multiple hydroxylation and methoxylation, resulting in several phenolic metabolites, most of which are converted to glucuronide conjugates. **Elimination:** Total clearance of Diclofenac from plasma is 263 ± 56 ml/min. The terminal plasma half-life is of 1-2 hours.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
01.	Cetomacrogol-1000	BP
02.	Carbomer (Carbopol-940)	BP
03.	Liquid Paraffin (H)	BP
04.	Propylene Glycol	BP
05.	Benzyl Alcohol	BP
06.	Isopropyl Alcohol	BP
07.	Diethylamine	IH
08.	Menthol	BP
09.	Essence Rose White (C8536)	IH
10.	Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not Freeze. Protect from light. Keep Out of reach of Children. Store at a temperature not exceeding 30°C.

6.5 Nature and contents of container

i) 20 g. in an Aluminium barrier Laminate tube in an inner carton.
ii) 30 g. in an Aluminium lacquered collapsible tube in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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Country	:	INDIA

8. MARKETING AUTHORISATION NUMBER

07991/08518/REN/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Oct 23, 2022.

10. DATE OF REVISION OF THE TEXT

01/01/2023