SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Nioclean AD Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clindamycin Phosphate BP Eq to clindamycin 1.0% & Adapalene BP 0.1%

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A milky White Colour semi-solid mass filled in a printed laminated tube.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Nioclean-AD Gel is indicated for topical application in the treatment of mild to moderate inflammatory acne vulgaris as well as non-inflammatory Acne, either alone or in combination with other anti-acne products and for the cutaneous treatment of acne vulgaris where comedones, papules and pustules predominate.

4.2. Posology and method of administration

Topical Administration (Administered via Skin) Apply Nioclean-AD (Clindamycin Phosphate & Adapalene Gel) once at night where acne lesions appear 5 min ahead of using the gel.

4.3. Contraindications

Nioclean-AD(Clindamycin Phosphate & Adapalene Gel) is contraindicated in individuals with a history of hypersensitivity to preparations containing Clindamycin, Lincomycin, Adapalene or any of the components of the preparation, a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

4.4. Special warnings and precautions for use

Nioclean-AD Use of the topical formulation of clindamycin results in absorption of the antibiotic from the skin surface. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin.

Diarrhea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of oral and parenteral therapy with clindamycin.

Adapalene should not be used on areas which have cuts or scrapes or on sunburnt skin or in eczema. Contact with the eyes, mouth or angles of the nose and other very sensitive areas of the body should be avoided. If accidental contact does occur, immediately wash with warm water. Avoid exposure to strong sunlight and artificial UV light. Use of sunscreen products and protective clothing over the treated area is recommended. Stop the use of Nioclean-AD in case of sensitivity or irritation.

PRECAUTIONS

General: Clindamycin should be prescribed with caution in atopic individuals.

- If a reaction suggesting sensitivity or chemical irritation occurs, use of the medication should be discontinued.
- Exposure to sunlight, including sunlamps, should be minimized during the use of Nioclean-AD(Clindamycin Phosphate & Adapalene Gel). Use of sunscreen products and protective clothing over treated areas recommended when exposure cannot be avoided.
- Avoid contact with eyes, lips, angles of nose, and mucous membranes. The product should not be applied to cuts, abrasions, eczematous skin, or sunburned skin.
- Certain cutaneous signs and symptoms such as erythema, dryness, scaling, burning, or pruritus, may be experienced during treatment. These are most likely to occur during the first two to four weeks and will usually lessen with continued use of the medication. Depending upon the severity of adverse events, patients should be instructed to reduce the frequency of application or discontinue use.

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

N/A

4.6. Fertility, pregnancy and lactation

Adapalene: Teratogenic effects-Pregnancy Category C

Clindamycin: Teratogenic effects-Pregnancy Category B

Pregnancy:

There are, however no adequate and well-controlled studies using Adapalene and Clindamycin in pregnant woman. Because animal reproductive studies are not always predictive of human response, Zitol CL (Clindamycin Phosphate & Adapalene Gel) should be used during pregnancy only if clearly needed.

Lactation:

It is not known whether Adapalene or Clindamycin is excreted in human milk following use of topical gel. However, orally and parenterally administered Clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be

made whether to discontinue nursing to discontinue the use of Zitol-CL (Clindamycin Phosphate & Adapalene Gel), taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children under the age of 12 has not been established.

4.7. Effects on the ability to drive and use machines

The effect of clindamycin and Adapalene on the ability to drive or operate machinery has not been systematically evaluated.

4.8. Undesirable effects

Local effects: Burning, itching, dryness, erythema and peeling.

Systemic effects: Cases of diarrhea, bloody diarrhea and colitis [including pseudomembranous colitis] have been reported as adverse reactions in patients treated with oral and parenteral formulations of clindamycin and rarely with topical clindamycin. Abdominal pain and gastrointestinal disturbances as well as gram-negative folliculitis have also been reported in association with the use of topical formulations of clindamycin. Adapalene may cause the following side effects at the site of application.

Common: may affect up to 1 in 10 people Dry skin, irritation of the skin, burning sensation of the skin, redness of the skin (erythema). Uncommon: may affect up to 1 in 100 people Local skin reaction (contact dermatitis), skin discomfort, sunburn, itching of the skin (pruritus), peeling skin (exfoliation), flare up of acne.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Pharmacy and Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9. Overdose

Guaiphenesin:

Excessive application of Clindamycin Phosphate & Adapalene Gel may result in severe irritation. In this event, discontinue use and wait until the skin has recovered. Topically applied adapalene is not generally absorbed in sufficient amounts to produce systemic effects. Excessive application of topically applied clindamycin may result in absorption of sufficient amounts to produce systemic effects.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Adapalene is a chemically stable, retinoid-like compound. Biochemical and pharmacological profile studies have demonstrated that Adapalene is modulator of cellular differentiation, keratinization, and inflammatory processes all of represent important features in the pathology of acne vulgaris. Mechanistically, Adapalene binds to specific retinoic acid nuclear receptors but does not bind to the cytosolic receptor protein. Although the exact mode of action of Adapalene is unknown, it is suggested that topical Adapalene may normalize the differentiation of follicular epithelial cells resulting in decreased microcomedone formation.

Although Clindamycin Phosphate is inactive in vitro, rapid in vitro hydrolysis converts this compound to clindamycin which has antibacterial activity. Clindamycin inhibits bacterial protein synthesis at the ribosomal level by binding to 50S ribosomal subunit and affecting the process of peptide chain initiation.

In in vitro studies indicated that Clindamycin inhibited all tested Propionibacterium acnes culture at a minimum inhibitory concentration (MIC) of 0.04 mg/ml. Cross-resistance has been demonstrated between Clindamycin and Erythromycin.

5.2. Pharmacokinetic properties

Absorption of Adapalene through human skin is low. Only trace amounts (<0.25mg/ml) of parent substance have been found in the plasma of acne patients following chronic topical application of Adapalene in controlled clinical trials. Excretion appears to be primarily by the biliary route.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Methyl Paraben
Phenoxyethanol
Disodium EDTA
Carbomer-940
Polysorbate 80
Polyethylene Glycol 400
Sodium Hydroxide
Propylene Glycol
Allantoin
Aloe Vera Gel
Compound HNS

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years.

6.4. Special precautions for storage

Store below 30°C.

Keep in a cool and dry place.

6.5. Nature and contents of container

15 gm lami tubes internally coated with an epoxy resin based lacquer and closed with a polypropylene cap.

6.6. Special precautions for disposal and other handling

No special requirements.

7. Marketing authorization holder

KLM Laboratories Pvt. Ltd.
1004, Hub Town Viva,
Western Express Highway, Jogeshwari (E), Mumbai - 400060 India

8. Marketing authorization number(s)

H2024/CTD8015/16892

9. Date of First Authorization

23rd February 2024

10. Date of revision of text

November 2024