

## ACNETOR AD

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only**

Abbreviated Prescribing information for ACNETOR AD [Clindamycin & Adapalene Gel]  
[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION: Clindamycin:** Clindamycin is a lincosamide antibiotic with primarily bacteriostatic action against Gram positive aerobes and wide range of anaerobic bacteria. **Adapalene:** The mode of action of adapalene is suggested to be a normalisation of differentiation of follicular epithelial cells resulting in decreased microcomedone formation.

**INDICATIONS:** ACNETOR AD is indicated for treatment of Acne vulgaris.

**DOSAGE AND ADMINISTRATION: Dose:** ACNETOR AD should be applied to the acne affected areas once a day before retiring and after washing. A thin film of gel should be applied, with the fingertips, avoiding the eyes and lips. Ensure that the affected areas are dry before application. Since it is customary to alternate therapies in the treatment of acne, it is recommended that the physician assess the continued improvement of the patient after three months of treatment with ACNETOR AD Gel. With patients for whom it is necessary to reduce the frequency of application or to temporarily discontinue treatment, frequency of application may be restored, or therapy resumed once it is judged that the patient can again tolerate the treatment. If patients use cosmetics, these should be non-comedogenic and non-astringent. Paediatric population: The safety and effectiveness of ACNETOR AD Gel have not been studied in children below 12 years of age. ACNETOR AD Gel should not be used in patients with severe acne. **Method of administration:** As directed by the Physician.

**CONTRAINDICATION:** ACNETOR AD is contraindicated in: (a) Individuals with a history of hypersensitivity to clindamycin, lincomycin, adapalene or to any of the excipients. (b) Pregnancy. (c) Women planning a pregnancy.

**WARNINGS & PRECAUTIONS: Clindamycin:** Topical clindamycin has very rarely been associated with pseudomembranous colitis; however, if diarrhoea occurs the product should be discontinued immediately. Should antibiotic associated colitis occur appropriate diagnostic and therapeutic measures (such as vancomycin treatment) should be taken immediately. Responses may not be seen for 4-6 weeks. Although the risk of systemic absorption following the administration of clindamycin is low, the potential for the development of gastrointestinal adverse effects should be taken into account when considering treatment in patients with a previous history of antibiotic-associated colitis, enteritis, ulcerative colitis or Crohn's disease. Prolonged use of clindamycin may cause resistance and/or overgrowth of non-susceptible bacteria or fungi although this is a rare occurrence. Cross resistance may occur with other antibiotics such as lincomycin and erythromycin. Contact with the eyes or the mucous membranes of the nose and mouth should be avoided. In the event of accidental contact with the eyes or mucous membranes bathe the affected area with copious amounts of cool water. **Adapalene:** If a reaction suggesting sensitivity or severe irritation occurs, use of the medication should be discontinued. If the degree of local irritation warrants, patients should be directed to use the medication less frequently, to discontinue use temporarily until symptoms subside or to discontinue use altogether. Adapalene should not come into contact with the eyes, mouth, angles of the nose or mucous membranes. If product enters the eye, wash immediately with warm water. The product should not be applied to either broken (cuts and abrasions), sunburnt or eczematous skin, nor should it be used in patients with severe acne, or acne involving large areas of the body. Exposure to sunlight and artificial UV irradiation, including sunlamps, should be minimised during use of adapalene. Patients who normally experience high levels of sun exposure and those with inherent sensitivity to sun, should be warned to exercise caution. Use of sunscreen products and protective clothing over treated areas is recommended when

exposure cannot be avoided. Methyl para-hydroxybenzoate (E218) and propyl para-hydroxybenzoate (E216) may cause allergic reactions which can possibly be delayed.

**DRUG INTERACTIONS: Clindamycin:** No interactions have been reported with topical clindamycin. **Adapalene:** There are no known interactions with other medications which might be used cutaneously and concurrently with Adapalene; however, other retinoids or drugs with a similar mode of action should not be used concurrently with adapalene. Adapalene is essentially stable to oxygen and light and is chemically non-reactive. Whilst extensive studies in animals and man have shown neither phototoxic nor photoallergic potential for adapalene, the safety of using adapalene during repeated exposure to sunlight or UV irradiation has not been established in either animals or man. Exposure to excessive sunlight or UV irradiation should be avoided. Absorption of adapalene through human skin is low and therefore interaction with systemic medications is unlikely. There is no evidence that the efficacy of oral drugs such as contraceptives and antibiotics is influenced by the cutaneous use of Adapalene. Adapalene has a potential for mild local irritation, and therefore it is possible that concomitant use of peeling agents, astringents or irritant products may produce additive irritant effects. However, cutaneous antiacne treatment e.g. erythromycin (up to 4%) or clindamycin phosphate (1% as the base) solutions or benzoyl peroxide water based gels up to 10% may be used in the morning when Adapalene is used at night as there is no mutual degradation or cumulative irritation.

**ADVERSE REACTIONS: Clindamycin:** Common: Dry Skin, Erythema, Skin Burning, Irritation Around Eyes, Acne Exacerbation and Pruritus. Uncommon: Painful Skin and Scaly Rash. **Adapalene:** Common: Skin Irritation, Skin Burning. Uncommon: Dermatitis Contact, Skin Discomfort and Sunburn. Unknown: Skin Swelling, Skin Hypopigmentation, Skin Hyperpigmentation, Eyelid Irritation, Eyelid Erythema, Eyelid Pruritus, Eyelid Swelling, Anaphylactic Reaction and Angioedema.

**MARKETED BY:**

**TORRENT**  
PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)