

## **Acticare®**

Clindamycin Phosphate and Tretinoin

### **Composition:**

Clindamycin Phosphate and Tretinoin

**Excipients:** Glycerin, carbomer , methyl parahydroxybenzoate, propyl parahydroxybenzoate, disodium edetate, citric acid, poly sorbate 80, butylhydroxy toluene, triethanolamine and purified water.

### **Properties:**

**Acticare®** gel (Clindamycin Phosphate and Tretinoin) is an antibiotic and retinoid combination gel product with two active ingredients.

### **Indications:**

**Acticare®** gel indicated for the topical treatment of acne vulgaris in patients 12 years or older.

### **Dosage and administration:**

A pea-sized amount should be applied to the entire face once daily at bedtime. Do not apply to eyes, mouth, angles of the nose, or mucous membrane.

### **Contraindications:**

Regional enteritis, ulcerative colitis, or history of antibiotic-associated colitis.

### **Precautions:**

- Clindamycin can cause severe colitis, which may result in death. The treatment should be discontinued if significant diarrhea occurs.
- Avoid exposure to sunlight and sunlamps. Wear sunscreen daily.
- The treatment is not for oral, ophthalmic or intravaginal use.
- **Pregnancy: Category C;** There are no well-controlled trials in pregnant women. The gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- **Lactation:** It is not known whether clindamycin or tretinoin is excreted in human milk after topical application. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
- **Pediatric:** Safety and effectiveness in pediatric patients below the age of 12 years have not been established.

### **Drug interactions:**

- Concomitant use of topical medications soaps and cosmetics with strong drying effect can increase skin irritation. Use with caution.
- The gel should not be used in combination with erythromycin – containing products.
- Neuromuscular blocking agents.

**Adverse reactions:**

Skin erythema, scaling, itching, burning, stinging, nasopharyngitis, pharyngolaryngeal pain, dry skin, cough, gastrointestinal symptoms, and sinusitis.

**Presentation:**

**Acticare® Gel:** Each gram of the gel contains clindamycin phosphate 1.2 % (12mg) and tretinoin 0.025% (0.25mg) in tubes of 30g& 45g.

**(This is a medicament - Keep medicaments out of the reach of children)**

I 227/0810

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Last update: 8/2010