

Product Information

CLINGARD*Anti-acne **Gel**

CLINDAMYCIN PHOSPHATE GEL

Description

CLINGARD* Topical Gel contains clindamycin phosphate USP, at a concentration equivalent to 10 mg clindamycin per gram. Clindamycin phosphate is a water-soluble ester of the semi-synthetic antibiotic lincomycin.

Clinical Pharmacology

Clindamycin phosphate is inactive *in vitro*. Rapid hydrolysis *in vivo*, converts this compound to the antibacterial active clindamycin. Clindamycin *in vitro* inhibits Propionibacterium acnes.

Indications and Usage

CLINGARD* Topical Gel is indicated in the treatment of acne vulgaris.

Contraindications

- Individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin,
- A history of regional enteritis or ulcerative colitis,
- A history of antibiotic-associated colitis.

How to use this medicine

Before applying this medicine, the affected areas should be washed thoroughly with warm water and soap. Then it should be rinsed well and dried.

While applying it, just enough medicine should be used to cover the affected area. The medicine should be applied to the whole area usually affected by acne, not just to the pimples themselves. This will help prevent new pimples from erupting.

One should not wash the acne-affected areas too often as this may dry the skin and make the acne worse. If the skin is oily, wash the face with a mild, bland soap 2 or 3 times a day.

Dosage and Administration

A thin film of CLINGARD* Topical Gel should be applied twice daily to the affected area.

Warnings & Precautions

- Severe colitis has been associated with orally and parenterally administered clindamycin, which may result in patient death. The topical formulation of clindamycin can result in absorption of the antibiotic from the skin surface. With the use of topical and systemic clindamycin, diarrhea, bloody diarrhea and colitis (including pseudomembranous colitis) have been reported.
- Whenever there is a significant diarrhea, the drug should be discontinued. If possible, large bowel endoscopy should be considered to establish a definitive diagnosis in cases of severe diarrhea.

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Antimotility agents like opiates and diphenoxylate with atropine may prolong and/or worsen the condition.

- History of stomach or intestinal disease (especially colitis, including colitis caused by antibiotics, or enteritis) - these conditions may increase the chance of side effects that affect the stomach and intestines.
- History of any unusual or allergic reaction to this medicine or any other clindamycin (taken by mouth or by injection) or to lincomycin.

Drug Interactions

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuro-muscular blocking agents. Therefore it should be used with caution in patients receiving such agents.

Pregnancy, Teratogenic effects

There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly indicated.

Nursing Mothers

It is not known whether clindamycin is excreted in human milk following use of CLINGARD*. 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 or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients under the age of 12 have not been established.

Elderly Use

Although there is no specific information comparing the use of this medicine in the elderly with use in other age groups, this medicine is not expected to cause different side effects or problems in older people than it does in younger adults.

Side Effects

Side effects include burning, itching, dryness, erythema, oiliness & peeling. Diarrhea, bloody diarrhea and colitis have been reported rarely with the topical formulations of clindamycin.

Abdominal pain, GI disturbances and gram-negative folliculitis have been reported in patients using topical formulations of clindamycin.

Storage

Keep out of reach of children. Store in a cool place. Do not freeze.

Presentation

CLINGARD* Topical Gel in tube of 15 grams.



Mfd. and Marketed in India by:
ZYG Pharma Pvt. Ltd.
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 Industrial Area, Pithampur,
 Dist. Dhar - 454 775. (M. P).

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55 mm

55 mm

1½ times enlarged design

Actual size - 140 mm x 55 mm