

# Lotion

## Clindasol

### (Clindamycin)

## کلینڈاسول لوشن (کلینڈاماسین)

#### COMPOSITION

Each ml contains:  
Clindamycin (as phosphate) .....10mg  
(USP specifications)

#### DESCRIPTION

Clindasol lotion contains clindamycin, Clindamycin is a semi-synthetic lincosamide antibiotic used in the treatment of a variety of serious infections due to susceptible microorganisms as well as topically for acne vulgaris.

#### MECHANISM OF ACTION

The mechanism through which topical clindamycin treats acne vulgaris is unclear, but may be related to its activity against Propionibacterium acnes, a bacteria that has been associated with acne.

#### INDICATIONS

Clindasol lotion is indicated for the treatment of acne vulgaris.

#### DOSE & ADMINISTRATION

Apply a thin film of lotion twice daily to the affected area.  
Shake well before Use.

#### PHARMACOKINETICS

Following multiple topical applications of clindamycin phosphate at a concentration equivalent to 10 mg clindamycin per mL in an isopropyl alcohol and water solution, very low levels of clindamycin are present in the serum (0–3 ng/mL) and less than 0.2% of the dose is recovered in urine as clindamycin. Although clindamycin phosphate is inactive in vitro, rapid in vivo hydrolysis converts this compound to the ant bacterially active clindamycin.

#### PRECAUTIONS

Oral and parenteral clindamycin, as well as most other antibiotics, have been associated with severe diarrhoea

and pseudomembranous colitis. Use of the topical formulation of clindamycin results in absorption of the antibiotic from the skin surface. Diarrhoea and colitis have been reported infrequently with topical clindamycin. Therefore, the physician should, nonetheless, be alert to the development of antibiotic-associated diarrhoea or colitis. If significant or prolonged diarrhoea occurs, the drug should be discontinued and appropriate diagnostic procedures and treatment provided as necessary. The lotion has an unpleasant taste and caution should be exercised when applying medication around the mouth. Topical clindamycin should be prescribed with caution to atopic individuals.

#### Pregnancy:

In clinical trials with pregnant women, the systemic administration of clindamycin during the second and third trimesters has not been associated with an increased frequency of congenital abnormalities. There are no adequate studies in pregnant women during the first trimester of pregnancy. Clindamycin should be used during the first trimester of pregnancy only if clearly needed.

#### Nursing Mothers:

It is not known whether clindamycin is excreted in human milk following use of lotion. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Clindamycin has the potential to cause adverse effects on the breastfed infant's gastrointestinal flora. If oral or intravenous clindamycin is required by a nursing mother, it is not a reason to discontinue breastfeeding, but an alternate drug may be preferred. Monitor the infant for possible adverse effects on the gastrointestinal flora, such as diarrhea, candidiasis (thrush, diaper rash) or rarely, blood in the stool indicating possible antibiotic-associated colitis.

#### SIDE EFFECTS

Seborrhoea, skin irritation, urticaria, dry skin, stinging of the eye, eye pain and contact dermatitis have been reported in association with the use of topical formulations

of clindamycin.

#### CONTRAINDICATIONS

Clindasol lotion is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin, a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

#### STORAGE & INSTRUCTIONS

Store below 30°C.

Protect from heat, sunlight and moisture. Do not freeze or refrigerate.

Keep away from the reach of children.

Shake well before use.

**To be sold on the prescription of a registered medical practitioner only.**

**FOR EXTERNAL USE ONLY.**

#### HOW SUPPLIED

30ml in plastic bottle.

خوراک و ہدایات:

دوا کو ۳۰ ڈگری سینٹی گریڈ درجہ حرارت سے نیچے رکھیں۔

دھوپ، گرمی، نمی اور منجمد ہونے سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

Manufactured by:

**PHARMA SOL**

**PRIVATE LIMITED**

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Lahore, Pakistan.