

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

---

## CLINMISKIN SOLUTION

---

### 1. Generic Name

Clindamycin Phosphate Topical Solution USP

### 2. Qualitative and quantitative composition

#### Composition:

Clindamycin Phosphate I.P.

equivalent to Clindamycin .....1.0% w/v

Suitable Base.....q.s.

The Excipients used are Nicotinamide, Aloe Vera Extract, Sodium Hydroxide, Methyl paraben, Propyl Paraben, Propylene Glycol, and Capryol Glycin.

### 3. Dosage form and strength

**Dosage form:** Solution

**Strength:** Clindamycin Phosphate 1.0 % w/v

### 4. Clinical particulars

#### 4.1 Therapeutic indication

Clinmiskin® Solution is indicated in the treatment of mild, moderate and severe acne vulgaris: alone or in combination with other antiacne products.

#### 4.2 Posology and method of administration.

Apply Clinmiskin® Solution as advised by physician. It is for external use only. Wash your hands before use. Wash and dry the whole area, apply a thin film once daily to the skin where acne lesions appear and use enough to cover the entire affected area. In case of contact with the eyes, mouth or nostrils, rinse it off immediately with plenty of water.

#### 4.3 Contraindications

Clinmiskin® Solution is contraindicated in individuals with a history of hypersensitivity to any of the ingredients in the preparation.

#### 4.4 Special warnings and precautions for use

##### PRECAUTIONS

Clinmiskin® Solution is to be prescribed with caution in atopic individuals.

#### 4.5 Drugs interactions

This medicine may have an interaction with antibiotics (clarithromycin, rifampin, erythromycin), anti-HIV drug (indinavir, nelfinavir, ritonavir), antifungals (itraconazole, ketoconazole) and antidepressant (nefazodone). Besides this, Clinmiskin Gel 20 gm should not be given with muscle relaxants like atracurium, cisatracurium, doxacurium, metocurine, mivacurium, pancuronium, pipecuronium, rapacuronium, rocuronium, succinylcholine, tubocurarine and vecuronium.

#### 4.6 Use in special population (such as Pregnant women, lactating women, paediatric patients, geriatric patients etc.)

### PREGNANCY:

There are no adequate and well controlled trials in pregnant woman. Clindamycin is to be used during pregnancy only if clearly needed

### NURSING MOTHERS:

It is not known whether Clindamycin is excreted in human milk. However, orally and parenterally administered Clindamycin has been reported to appear in breast milk. Nursing should not be undertaken when the patient is on Clindamycin.

#### **4.7 Effects on ability to drive and use machines**

Not applicable

#### **4.8 Undesirable effects:**

Local Effects: Contact dermatitis, irritation (erythema, peeling and burning), Gram negative folliculitis.

Systemic Effects: Occasional abdominal pain and Gastro-intestinal disturbances.

#### **Reporting of adverse reactions**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: [https://www.torrentpharma.com/index.php/site/info/adverse\\_event\\_reporting](https://www.torrentpharma.com/index.php/site/info/adverse_event_reporting)

#### **4.9 Overdose**

Not available

### **5 Pharmacological properties**

#### **5.1 Mechanism of Action**

Clindamycin acts by inhibiting bacterial protein synthesis at the level of the 50S ribosome. As a result, it exerts a prolonged postantibiotic effect. It may decrease toxin production and increase microbial opsonization and phagocytosis even at subinhibitory concentrations.

#### **5.2 Pharmacodynamic properties**

In *Vitro*, Clindamycin has been found to have activity against isolates of *Propionibacterium acnes*. The antibacterial activity of Clindamycin has been demonstrated in comedones from acne patients. The MIC of Clindamycin is 0.4 mcg/ml. free fatty acids on the skin surface decrease from 14% to 2% after application of Clindamycin. Aloe is a skin rejuvenator, promotes faster healing of acne, reduces scar formation and makes skin soft and glowing.

#### **5.3 Pharmacokinetic properties**

Not applicable

### **6 Nonclinical properties**

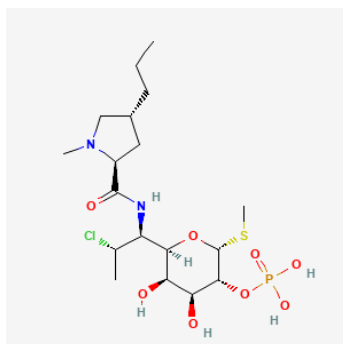
#### **6.1 Animal Toxicology or Phamacology**

Not applicable

### **7 Description**

#### **Clindamycin Phosphate:**

Clindamycin Phosphate is methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4R)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-1-thio-L-thero- $\alpha$ -D-galacto-octopyranoside 2-(dihydrogen phosphate). The Empirical formula is  $C_{18}H_{34}ClN_2O_8PS$  and its molecular weight is 505.0 g/mol. The chemical structural formula is:



### **CLINMISKIN SOLUTION:**

Clindamycin Phosphate Topical Solution is Clear Transparent Solution. The Excipients used are Nicotinamide, Aloe Vera Extract, Sodium Hydroxide, Methyl paraben, Propyl Paraben, Propylene Glycol, and Capryol Glycin.

#### **8 Pharmaceutical particulars**

##### **8.2 Incompatibilities**

None known.

##### **8.3 Shelf-life**

Do not use later than date of expiry

##### **8.4 Packaging information**

**CLINMISKIN SOLUTION** is available in pack of 30 ml.

##### **8.5 Storage and handing instructions**

Do not store above 30<sup>0</sup>C. Store in a dry and dark place.

For external use only.

#### **9 Patient Counselling Information**

##### **CLINMISKIN SOLUTION**

(Clindamycin Phosphate Topical Solution USP)

Read all of this leaflet carefully before you start taking this medicine because it contains Important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others; it may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side Effects not listed in this leaflet.

What is in this leaflet?

## **9.2 What CLINMISKIN SOLUTION is and what it is used for**

## **9.3 How to apply CLINMISKIN SOLUTION.**

## **9.4 Possible side effects**

## **9.5 How to store CLINMISKIN SOLUTION.**

## **9.6 Contents of the pack and other information**

### **9.1 What CLINMISKIN SOLUTION is and what it is used for**

CLINMISKIN SOLUTION contain Clindamycin Phosphate Topical Solution, it is used for the treatment of mild, moderate and severe acne vulgaris: alone or in combination with other antiacne products.

### **9.2 How to apply CLINMISKIN SOLUTION.**

Wash and dry the whole area, apply a thin film once daily to the skin where acne lesions appear and use enough to cover the entire affected area.

### **9.3 Possible side effects**

Local Effects: Contact dermatitis, irritation (erythema, peeling and burning), Gram negative folliculitis.

Systemic Effects: Occasional abdominal pain and Gastro-intestinal disturbances.

### **9.4 How to store CLINMISKIN SOLUTION.**

Do not store above 30<sup>0</sup>C. Store in a dry and dark place.

### **9.5 Contents of the pack and other information**

**CLINMISKIN SOLUTION** content of Clindamycin Phosphate as Active ingredients.

The Excipients used are Nicotinamide, Aloe Vera Extract, Sodium Hydroxide, Methyl paraben, Propyl Paraben, Propylene Glycol, and Capryol Glycin.

**CLINMISKIN SOLUTION** is available in pack of 30 ml.

## **10 Details of manufacturer**

Sankalp Healthcare And  
Allied Products Private Limited,  
Plot No. A-16, M.I.D.C., Tasavade,  
Karad, Dist. Satara – 415 109,  
Maharashtra, India.

## **11 Details of permission or licence number with date**

Mfg. Licence No.: PD/89 Issued on: 16.07.2018

## **12 Date of revision**

NA

**MARKETED BY**



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

**IN/CLINMISKIN SOLUTION 30 ml/NOV-23/PI/01**