

Utoclind **Vaginal Cream**

Company Name:

Utopia Pharmaceuticals.

Composition:

Each 1gm contains:

Active Ingredients:

Clindamycin phosphate 23.76 mg equivalent to 20 mg clindamycin.

Inactive Ingredients:

- Cetostearyl alcohol
- Cetomacrogel 1000 (Brij58)
- White soft paraffin
- Heavy soft paraffin

- Dibasic sodium phosphate
- Citric acid anhydrous
- Chlorocresol
- Purified water .

Pharmacological Action:

Clindamycin is an antibacterial agent which has been shown to be effective in the treatment of infections caused by susceptible anaerobic bacteria or susceptible strains of gram positive aerobic bacteria. It has been shown to have an activity against the following organisms which are associated with bacterial vaginitis:

- Gardnerella vaginalis
- Mobiluncus spp
- Bacteroides spp
- Mycoplasmas hominis
- Peptostreptococcus spp.

Pharmacokinetics:

Following once a day dosing of 100mg of vaginally administered clindamycin phosphate, peak serum approximately 4% of the administered dose is absorbed systemically.

- In women with bacterial vaginosis, the amount of clindamycin absorbed following vaginal administration of 100mg of clindamycin vaginal cream is 5% which is nearly the same as in healthy women (clindamycin levels average 20 mg/ml in healthy women.)

Indications:

- In bacterial vaginosis (formerly referred to hemophilus vaginitis gardnerella, nonspecific vaginitis, corynebacterium vaginitis or anaerobic vaginitis).
- Trichomonas vaginalis and candida albicans infections with chlamydia trachomatis.
- Gonococcal infections should be ruled out, before handed, by appropriate laboratory methods.

Dosage:

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One applicator full of cream (approximately 5gm of vaginal cream containing 100mg of clindamycin phosphate) administered once per day intravaginally for 3-7 consecutive days at bedtime or as per the physician's recommendation.

Over Dosage:

- Intravaginal over dosage is not possible.
- Accidental ingestion of the product could be accompanied by effects related to therapeutic levels of oral clindamycin.

Contraindications:

Utoclind vaginal cream should not be used by patients who are hypersensitive to clindamycin, to another component of the product or to lincomycin.

Adverse Effects:

The safety of cream was evaluated in non-pregnant patients and in women during their second and third trimester of pregnancy.

- The following product-related adverse drug reactions have been reported in <10% of the patients:

Non-pregnant Patients:

- Genital tract: cervicitis/vaginitis (16%), constipation by candida albicans (11%), Trichomonas vaginalis (1%), vulvar irritation (6%).
- Central nervous system: dizziness, headache and vertigo.
- Gastrointestinal: heartburn, nausea, vomiting, diarrhea, constipation, abdominal pain and risk of pseudomembranous colitis.
- Dermatologic: rash.
- Hypersensitivity: urticaria.

Pregnant Patients:

- Genital tract: symptomatic vaginitis/yeast infection (15.6%), vulvovaginal irritation (7.2%), vaginal itching.
- Urinary tract: dysuria
- Dermatologic: pruritus/itching (1.7%) and erythema.

Adverse drug reactions without percentages were confirmed in less than 1% of the patients.

Pregnancy:

- There are no adequate and well controlled studies of clindamycin in pregnant women.
- Clindamycin should be used during pregnancy only if clearly needed and is preferred to be used in the second

& third trimesters.

Lactation:

It is not known if clindamycin is excreted in breast milk following the use of vaginally administered clindamycin phosphate. However, following oral and parenteral administration, clindamycin was found in breast milk. It should be noted that following vaginal administration of clindamycin vaginal cream serum levels are about 200 times lower than following oral or parenteral administration. Furthermore, clindamycin can be used safely in neonates. Nevertheless, benefits should be outweighed against risks before switching to vaginal clindamycin phosphate in a nursing mother.

Drug Interactions:

- Concomitant use with other intra-vaginal products is not recommended.
- Cross resistance has been demonstrated between clindamycin and lincomycin .
- Antagonism has been demonstrated between clindamycin and erythromycin .

Precautions & Warnings:

- The use of clindamycin may result in the overgrowth of non susceptible organisms, particularly yeasts.
- Orally, parenterally and vaginally administered clindamycin, like nearly all other antibiotics, has been associated with diarrhea, and in some cases with pseudomembranous colitis.
- Only minimal absorption (approximately 4%) of clindamycin occur following the use of clindamycin intravaginally; however, if significant or prolonged diarrhea occurs, the drug should be discontinued and appropriate diagnostic procedures and treatment provided as necessary.
- As with all vaginal infections, it is not recommended to have sexual intercourse during the infection, it is preferable to wait 2 hours minimum after applying the cream.
- The use of cream has not been studied in patients under 16 years of age.

Instructions for Patients:

Open the tube; screw a plastic applicator on to the end of the tube; push softly at the bottom of the tube in order to fill the applicator with cream until you experience resistance; the plunger is now pushed out of the applicator for the greater part; unscrew the applicator; close the tube.

While the patient is lying on her back, insert the applicator deeply into the vagina and inject the cream. Dispose the applicator after use.

For vaginal use only.

Package:

Carton box containing a plastic tube of 20g + 3 sterile plastic separated applicators (5gm) + the insert leaflet.

Storage:

- Store at a temperature not exceeding 25°C.
- keep out of reach of children.

Produced by Medizen Pharmaceutical Industries for Utopia Pharmaceuticals.