# TORGYN®

## Clindamycin 100 mg

## Vaginal Soft capsules

Made in Argentina
Rx only

QUALIQUANTITATIVE FORMULA

Each soft capsule contain:

| | |
|---|---|
| Clindamycin Phosphate | 118.822 mg |
| ( equivalent to Clindamycin | 100 mg ) |
| Dimethicone | 3.150 mg |
| Mineral oil | 479.237 mg |
| Paraffin | 1498.793 mg |

THERAPEUTIC ACTION

Bactericide antibiotic for intravaginal topical use
ATC Code: G01A A10

INDICATIONS:

It is indicated for the treatment of bacterial vaginosis formerly called vaginitis by haemophylus, vaginitis by Gardnerella, non- specific vaginitis, vaginitis by Corinebacterium, or anaerobe vaginoses.

Other pahogens commonly associated with vulvovaginitis, as for example, Chlamydia, trachomatis, trichomonas vaginalis, N. gonorrhoeae, candida albicans and Herpes simplex shall be exempted previous to starting the treatment.

PHARMACOLOGICAL ACTION

Clindamycin phosphate is a water soluble ester of the semi-synthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent antibiotic Lincomycin.
Clindamycin inhibits the bacterial proteic synthesis due to its action in the bacterial ribosome. The antibiotic combines preferably with the sub ribosomic unit 50S and affects the process of initiation of the peptide chain. Even when the Clindamycin phosphate is not active in vitro, the fast hydrolysis in vitro turns this compound into antibacterial active Clindamycin.

Clindamycin is an active antimicrobial agent in vitro against most of the strains of the following organisms which are associated with the bacterial vaginosis:
Bacteroids spp, Gardnerella vaginalis, Mobiluncus spp, Mycoplasma hominis, Peptostreptococcus.

PHARMACOKINETICS

About 2 and 8 % of the vaginally administered dose passes to the systemic flow.

POSOLOGY, DOSAGE, AND ADMINISTRATION:

Apply an soft capsule deep into the vaginal cavity during 7 consecutive days.

According to medical criteria, the treatment may last 3 days (One intravaginal soft capsule during 3 consecutive days).

CONTRAINDICATIONS

Contraindicated in patients with a history of hypersensitivity to Clindamycin, Lyncomicin or any of the components of the formulation.
It is also contraindicated in persons with history of regional enteritis, ulcerous colitis or a history of colitis "associated to antibiotics".

WARNINGS

Pseudomembranose colitis has been reported in almost all the antibacterial agents, including Clindamycin and its severity may vary from slight until constituting a risk for the life when it is administered orally or parenterally.

Diarrhea, bleeding diarrhea or colitis, (including psudomembranose colitis) have been reported with the use of Clindamycin in oral and parentheral administration, as well as topic formulas (dermic) of Clindamycin. Thus, it is important to consider this diagnose in patients presenting diarrhea following the administration of Clindamycin even via vaginal administration, because approximately the 5 % of the dose of Clindamycin is absorbed systemically inside the vagina.

After what has been established in the diagnose of colitis pseudomembranose, therapeutic measures must be initiated. Mild cases of colitis pseudomembranose commonly respond to the discontinuation of the drug alone. In moderate to severe cases, caution must be exercised when handling liquids and electrolytes, proteic supplement, and the treatment with a clinically effective antibacterial drug against colitis by Clostridium difficile. The onset of symptoms of psudomembranose colitis may occur during or after the antimicrobial treatment.

CAUTION

The product contains excipients that cause burn and ocular irritation. In case of accidental contact with the eyes, rinse them abundantly with cold tap water.

The use of Clindamycin phosphate soft capsules may result into the development of a non susceptible organism, particularly vaginal candidiasis.

Sexual intercourse is to be avoided during the treatment with these products.

INTERACTIONS

Clindamycin has shown to have properties of neuromuscular blockage which may increase the action of other neuromuscular blocking agents. Therefore, it must be used with caution in patients receiving such agents.

CARCINOGENESIS, MUTAGENESIS AND FERTILITY DISORDERS

No long term studies have been carried out in animals with Clindamycin for the evaluation of the carcinogenic potential. The genotoxicity tests carried out included a micronucleous test in rat and an Ames test. Both tests were negative. The fertility tests in rats treated orally with up to 300 mg/kg/day (31 times the human dose based on mg/m2) did not reveal any effects over the fertility or mating capacity.

Pregnancy: reproduction studies in rats and mice have been carried out using oral and parenteral doses of Clindamycin of up to 600 mg /kg/day ( 62 and 25 times respectively the maximum human dose based on mg/m2) and have not revealed evidence of fetal damage with Clindamycin. In a breed of mice treated with Clindamycin split palates were observed in the litter. This result was not observed in other murin breed or species, and therefore, it is considered as a specific effect of that breed.

However there are no adequate or well controlled studies in pregnant women. Since the studies of animal reproduction are not always a diagnose of human response, this drug can be used during pregnancy if absolutely necessary.

Nursing: It is unknown if Clindamycin is excreted in human milk following the use of Clindamycin phosphate for vaginal administration. However after the oral or parenteral administration, Clindamycin has been discovered in the human milk.

Due to potential serious adverse reactions in breastfeeding infants due to Clindamycin phosphate, a decision must be made whether nursing or the drug must be discontinued considering the importance of the drug for the mother.

Pediatric use: Safety and efficiency have not been established in infant girls.

ADVERSE REACTIONS:

Genital Tract:

Cervicitis / Symptomatic vaginitis (16%), Candida Albicans (11 %) , Vaginal Tricomones (1 %), Vulvar Irritation (6 %) .

Central Nervous System:

Confusion, Cephalea, Vertigo.

Dermatological

Rash

Gastrointestinal

Pirosis, Nausea, Vomit, Diarrhea, Constipation Abdominal pain

Hipersensitivity

Rash

Other formulas of Clindamycin

Other effects that have been reported in association with the use of topical (dermal) formulas of Clindamycin include: severe colitis (including pseudomembranose colitis), dermathitis by contact, irritation of the skin (for example erythema, flaking and burn), oily skin, foliculitis by negative gram germs, abdominal pain, and gastrointestinal disorders.

Clindamycin soft capsules produce minimum peak levels in serum and systemic exposition (AUC) of Clindamycin in comparison with 100 mg of oral Clindamycin.

Even if these lowest levels of exposition are less likely to produce common seen reactions with oral Clindamycin, currently you cannot exclude the possibility of these and other reactions.

The information obtained with these controlled test that compare directly Clindamycin in oral administration with Clindamycin in vaginal administration are not available.

The following adverse reactions and altered laboratory tests have been reported with the oral or parentheral use of Clindamycin.

Gastrointestinal

Abdominal Pain , Esofagitis, Nausea, Vomit , Diarrhea
( See warnings).

Hematopoietic

Transient Neutropenia (leucopenia)
Eosinophilia
Agranulocythosis

Thrombocitopenia

In none of these reports an ethyological ratio could be established with the concurrent therapy with Clindamycin.

Hypersensitivity Reactions

Maculo-papular rash and itch have been observed during the therapy with the drug, mild to moderate generalized skin rashes of the morbiliform type are the most frequent reported adverse reactions.

Rare cases of multiform erythema, some of them similar to Stevens Johnson Syndrome have been associated with Clindamycin. A few cases of anafilactoid reactions have been reported. If a hypersensitivity reaction is produced, the drug must be discontinued.

Liver

Jaundice has been reported during therapy with Clindamycin and anomalies of the tests of the hepatic functions.

Muscle – Skeletal

Rare cases of poly arthritis have been reported.

Kidney

Even if a direct relationship has not been established of clindamicine with kidney damage, in very few cases, renal disfunction has been reported as evidenced by hyperazohemia, oliguria and/or proteinuria.

OVERDOSE

Clindamycin phosphate vaginal soft capsules can be absorbed in enough quantities so as to produce systemic effects (see Warnings).

IN THE EVENT OF AN OVERDOSE GO TO THE NEAREST HOSPITAL OR COMMUNICATE WITH THE TOXICOLOGY CENTERS.

HOW SUPPLIED:
BLISTERS CONTAINING 3 AND 7 VAGINAL SOFT CAPSULES.

STORAGE:
At room temperature (15 to 30°C), protect from freezing.

MEDICINAL SPECIALTY AUTHORIZED BY THE MINISTRY OF HEALTH.
Certificate Nr: 45972

TECHNICAL DIRECTOR: Marina Manzur Pharmacist

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KEEP OUT OF REACH OF CHILDREN

THIS MEDICATION SHALL ONLY BE USED UNDER STRICT SURVEILLANCE AND MEDICAL CONTROL AND CANNOT BE REPEATED WITHOUT A NEW PRESCRIPTION.

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