

NAPO VAG C
Clindamycin & Clotrimazole
Vaginal Soft Gelatin Capsules

COMPOSITION:

Each Vaginal Soft Gelatin Capsule Contains:

Clindamycin Phosphate BP	
Eq. to Clindamycin	100 mg
Clotrimazole BP	200 mg
Excipients	q.s.

Approved Colours Used in Softgel Capsule Shell.

DESCRIPTION

NAPO VAG C is indicated in the treatment of bacterial vaginosis and other gynecologic infections caused by bacteria and fungi susceptible to the product.

PHARMACODYNAMICS

Clindamycin Phosphate:

Clindamycin works primarily by binding to the 50s ribosomal subunit of bacteria. This agent disrupts protein synthesis by interfering with the transpeptidation reaction, which thereby inhibits early chain elongation.

Clindamycin may potentiate the opsonization and phagocytosis of bacteria even at subinhibitory concentrations. By disrupting bacterial protein synthesis, clindamycin causes changes in the cell wall surface which decreases adherence of bacteria to host cells and increases intracellular killing of organisms.

Clotrimazole:

Clotrimazole is an antifungal medication commonly used in the treatment of fungal infections of both humans and animals such as vaginal yeast infections, oral thrush, and ringworm. It is also used to treat athlete's foot and jock itch. Clotrimazole is a broad-spectrum antifungal which binds to phospholipids in the cell membrane altering cell wall permeability causing a loss in essential intracellular elements.

PHARMACOKINETICS

Clindamycin Phosphate:

Absorption: ~10% of topically applied drug is absorbed systemically. No significant levels are seen in CSF, even with inflamed meninges; crosses the placenta; distributes into breast milk; high concentrations in bone and urine.

Metabolism: Hepatic

Elimination: Most of drug eliminated by hepatic metabolism

Clotrimazole:

Absorption: Negligible through intact skin (topical); 3-10% (vaginal).

Metabolism Hepatic; converted to inactive metabolites.

Excretion Urine, faeces (as metabolites).

THERAPEUTIC INDICATIONS

Clindamycin and Clotrimazole Capsules is indicated in the treatment of bacterial vaginosis, candidiasis and other gynecologic infections caused by bacteria and fungi susceptible to the product. Sanitation of genital tracts prior gynecologic procedures.

POSODOGY AND METHOD OF ADMINISTRATION

One softgel capsule should be inserted into the vagina at night preferably before retiring to bed. Treatment should be timed so as to avoid the menstrual period. **ONLY FOR VAGINAL INSERTION. NOT FOR ORAL USE.**

Treatment of Bacterial Vaginosis and other gynecological infection: 1 Capsule a day for 7 days before sleep.

Profilaxis before gynecological procedures: 1 capsule a day for 3 days before the planned gynecological procedures and 4 days after the procedures.

CONTRAINDICATION

Hypersensitivity to the components of the preparation.

Clindamycin Phosphate:

Clindamycin 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.

Clotrimazole:

Hypersensitivity to imidazole. First trimester of pregnancy Caution when used during pregnancy & lactation.

SPECIAL WARNING AND PRECAUTION FOR USE

It is not recommended to use Clindamycin and Clotrimazole Capsule during menstruation. If in process of use of Clindamycin and Clotrimazole Capsule the apparent or long term diarrhoea occurs, the treatment should be stopped, the appropriate diagnostic procedures are to be taken, and the treatment should be prescribed, if necessary. During treatment with vaginal capsule vaginal intercourse and use of other products with intravaginal route of introduction are not recommended.

If irritation or sensitivity develops with the use of Clotrimazole, treatment should be discontinued and appropriate therapy instituted.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

The antagonist effect is possible between Clindamycin and erythromycin; Clotrimazole, if introduced intravaginally, depresses the activity of amphotericin B and other polyene antibacterial agents. If used at the same time with nystatin the effect of

Clotrimazole may be suppressed. Clindamycin Phosphate and Clotrimazole Capsule contain the components which may deteriorate reliability of the latex and rubber products, such as are the condoms or contraceptive vaginal diaphragms. That's why it is not recommended to use these products in process of treatment.

PREGNACY & LACTATION

There are no adequate and well controlled studies in pregnant women.

This drug should be used only if clearly indicated during the first trimester of pregnancy.

It is not known whether this drug passes into breast milk.

Although intravaginal application of Clotrimazole has shown negligible absorption from both normal and inflamed human vaginal mucosa, Clotrimazole vaginal preparations should not be used in the first trimester of pregnancy unless the physician considers it essential to the welfare of the patient.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None reported.

UNDESIRABLE EFFECTS

Clindamycin phosphate:

Genital itching or burning, irritation, vaginal pain.

Seek medical attention right away if any of these SEVERE side effects occur:

Severe allergic reactions (rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips, or tongue), blood/mucus in stools, diarrhea, new or worsening vaginal or vulvar itching, painful sex, severe stomach cramps, white vaginal discharge.

Clotrimazole:

Pruritus, erythema, stinging, blistering, peeling, edema, urticaria, burning, general skin irritation, rash

OVERDOSE

Symptoms of overdose may include: severe headache, tiredness, dizziness, mental/mood changes (such as irritability, depression), vision changes (such as double vision, blurred vision), dry/peeling skin, bone/joint pain, loss of appetite, yellowing skin/eyes, dark urine, severe stomach/abdominal pain.

INCOMPATIBILITY

Not applicable.

SHELF LIFE

36 months

PACKAGING

7 softgels are packed in Alu-PVC blister. such 1 blister is packed in printed monocarton along with

applicator & pack insert; such 10 monocartons are packed in printed outer carton.

STORAGE:

Store at a temperature below 30°C. Protect from direct sunlight, heat and moisture.

Keep the medicine out of reach of children.



ALWAYS BEST EFFICIENT EFFECTIVE RESULT

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