VEGACIN VAGINAL CREAM

Clindamycin 2%
For intravaginal use only | 40 g tube

COMPOSITION

Each 1 g of vaginal cream contains clindamycin phosphate equivalent to **20 mg clindamycin (2% w/w)**, assuming the approved formulation uses clindamycin phosphate. Each 5 g applicatorful delivers approximately 100 mg clindamycin. Excipients: as per approved product specification.

THERAPEUTIC CLASS

Lincosamide antibiotic; intravaginal antibacterial agent. **Primary segment:** Gynecology and women's health.

PHARMACOLOGY

Clindamycin binds to the bacterial 50S ribosomal subunit and inhibits protein synthesis. It is active against several organisms associated with bacterial vaginosis. A small proportion of the vaginal dose may be absorbed systemically.

INDICATIONS

Treatment of bacterial vaginosis in appropriately diagnosed patients. Evaluate other causes of vaginitis, including candidiasis, trichomoniasis and sexually transmitted infections, as clinically indicated.

DOSAGE AND ADMINISTRATION

A commonly approved regimen for clindamycin 2% vaginal cream is **one full applicator (approximately 5 g) intravaginally at bedtime for 7 consecutive days**. Some reference products permit 3-day treatment in nonpregnant patients; the 7-day course is used for pregnant patients where indicated. Follow the locally approved Vegacin regimen.

DIRECTIONS FOR USE

Wash hands. Remove tube cap and attach the supplied applicator. Gently squeeze cream into the applicator until filled to its designated stop. Unscrew applicator and replace tube cap. Lie on the back with knees bent; gently insert applicator into the vagina as far as comfortable and depress plunger fully. Remove and discard single-use applicator. Wash hands.

IMPORTANT USE INSTRUCTIONS

For intravaginal use only. Not for oral, skin or eye use. Avoid contact with eyes. Complete the prescribed course even if symptoms improve. Do not share the product. If a dose is missed, contact the prescriber or follow approved product instructions; do not use double doses.

CONTRAINDICATIONS

Hypersensitivity to clindamycin, lincomycin or formulation ingredients. History of regional enteritis, ulcerative colitis or antibiotic-associated colitis, including C. difficile-associated colitis.

WARNING: SEVERE DIARRHEA / COLITIS

Clindamycin can cause C. difficile-associated diarrhea and pseudomembranous colitis, including after vaginal use. Stop treatment and seek urgent medical assessment if severe, persistent or bloody diarrhea, abdominal cramps or fever develops during or after treatment.

PRECAUTIONS

Vaginal clindamycin may promote overgrowth of nonsusceptible organisms, including yeast. If symptoms persist or recur, reassess the diagnosis. Avoid intercourse, tampons, douches and other intravaginal products during therapy unless otherwise directed.

LATEX AND RUBBER PRODUCTS

Cream bases containing mineral oil may weaken latex or rubber condoms and diaphragms. For conventional clindamycin phosphate 2% vaginal cream, avoid relying on such barrier products during treatment and for **72 hours after completion**; verify the restriction against the approved Vegacin excipient formulation.

DRUG INTERACTIONS

Clindamycin has neuromuscular blocking properties and may enhance the effects of neuromuscular blocking agents. Antagonism with erythromycin has been demonstrated in vitro. Tell the prescriber about other medicines and vaginal products.

PREGNANCY AND LACTATION

Use in pregnancy only on medical advice following assessment of benefits and risks. Some reference labels support use in the second and third trimesters when indicated; first-trimester data are limited. It is unknown whether vaginal administration results in clinically relevant breast-milk levels; use caution while breastfeeding.

ADVERSE REACTIONS

Vaginal candidiasis, vulvovaginal irritation or discomfort, vaginal discharge, itching, headache, abdominal pain and nausea may occur. Serious adverse effects include hypersensitivity and antibiotic-associated colitis. Seek care for severe rash, swelling, breathing difficulty or significant diarrhea.

OVERDOSAGE

Excessive vaginal use may increase systemic absorption and adverse effects. If accidentally swallowed or substantial overdose is suspected, seek medical advice. Management is supportive.

STORAGE

Reference clindamycin phosphate 2% vaginal creams are stored at **20–25°C** and protected from freezing. Confirm the approved Vegacin storage specification before printing. Keep tightly closed and out of reach of children.

PRESENTATION

Vegacin Vaginal Cream 2%: **40 g tube**. Applicator supply and quantity must match the approved commercial pack.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.