

Because women with bacterial vaginosis (BV) need

Effectiveness and convenience in one



Clindesse[®]
(clindamycin phosphate) Vaginal Cream, 2%
JUST ONE & DOSING'S DONE

For patients with bacterial vaginosis (BV)

Just one & dosing's done

Clindesse® delivers efficacy and one-dose convenience^{1,2}

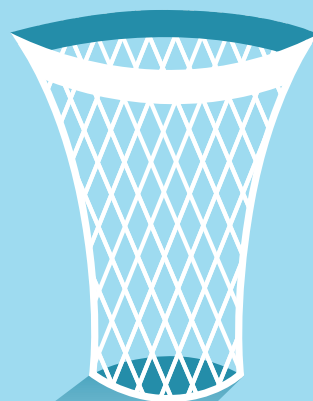
- 88% efficacy based on resolution of 3 of 4 Amsel criteria¹
- Broad-spectrum activity against the most common BV pathogens^{*3-9}
- Fast symptom relief¹⁰
- One-dose convenience may enhance compliance
- In a survey of more than 12,000 women, 97% of Clindesse users would use it again¹⁰

*In vitro activity may not necessarily correlate with clinical results.

Clindesse is indicated for the treatment of bacterial vaginosis in non-pregnant women. Clindesse is Pregnancy Category B, which means there are no adequate and well-controlled studies in pregnant women. Therefore, Clindesse should be used during pregnancy only if clearly needed.

Clindesse is contraindicated in individuals with a history of hypersensitivity to clindamycin, lincomycin, or any of the components of this vaginal cream, and in individuals with a history of regional enteritis, ulcerative colitis, or a history of "antibiotic-associated" colitis.

For important safety information, please see safety section and full prescribing information.



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Broad-spectrum therapy targeting the most common BV pathogens

Clindamycin, the active agent in Clindesse®, provides broad-spectrum therapy against the most common BV pathogens*3-9

- BV is a complex polymicrobial infection that results from an overgrowth of a number of different bacterial species
 - Based on a clinical study, women with BV have, on average, 13 different species implicated in their infection¹¹

Clindamycin has demonstrated better *in vitro* activity than metronidazole against the most common pathogens implicated in BV*

<i>Gardnerella vaginalis</i> ^{3,4}	Present in 99% of BV infections ¹²
<i>Mobiluncus</i> spp ^{3,5-7}	Present in 50% of BV infections ¹³
<i>Mycoplasma hominis</i> ^{3,5,14}	Present in up to 58% of BV infections ¹²
<i>Atopobium vaginae</i> ^{†8,9}	Present in 61% of BV infections ¹⁵

- Clindamycin has demonstrated effective *in vitro* activity against the most common BV pathogens*3-9
- *Gardnerella vaginalis*, *Mobiluncus* spp, *Mycoplasma hominis*, and *Atopobium vaginae* have demonstrated *in vitro* resistance to metronidazole*3,4,6,8,14,16
- Clindesse and MetroGel-Vaginal® have demonstrated similar levels of lactobacilli restoration at 21–30 days¹⁷

**In vitro* activity may not necessarily correlate with clinical results.

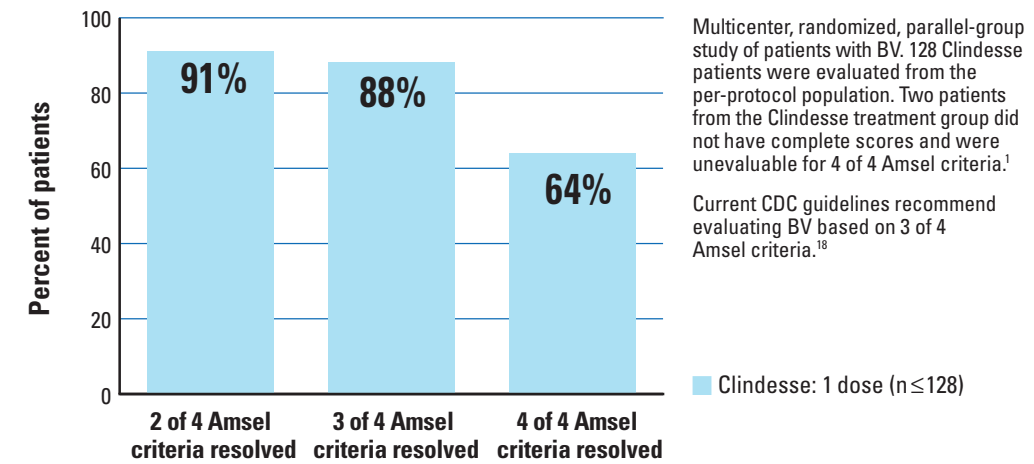
†N=73. Women without BV had an average of 3 different species (n=46).

‡In 2004, Ferris published "Association of *Atopobium vaginae*, a recently described metronidazole resistant anaerobe, with bacterial vaginosis."⁸

MetroGel-Vaginal® is a registered trademark of 3M Pharmaceuticals.

Clindesse delivers efficacy and fast symptom relief^{1,10}

Clindesse efficacy for BV based on resolution of Amsel criteria¹



Clindesse effectively relieves the vaginal odor associated with BV in just 1.5 days, based on clinical trial patient diaries^{5,10}

- Untreated asymptomatic patients will often develop a malodorous discharge¹⁹

⁵Median time to relief for modified intent-to-treat population.



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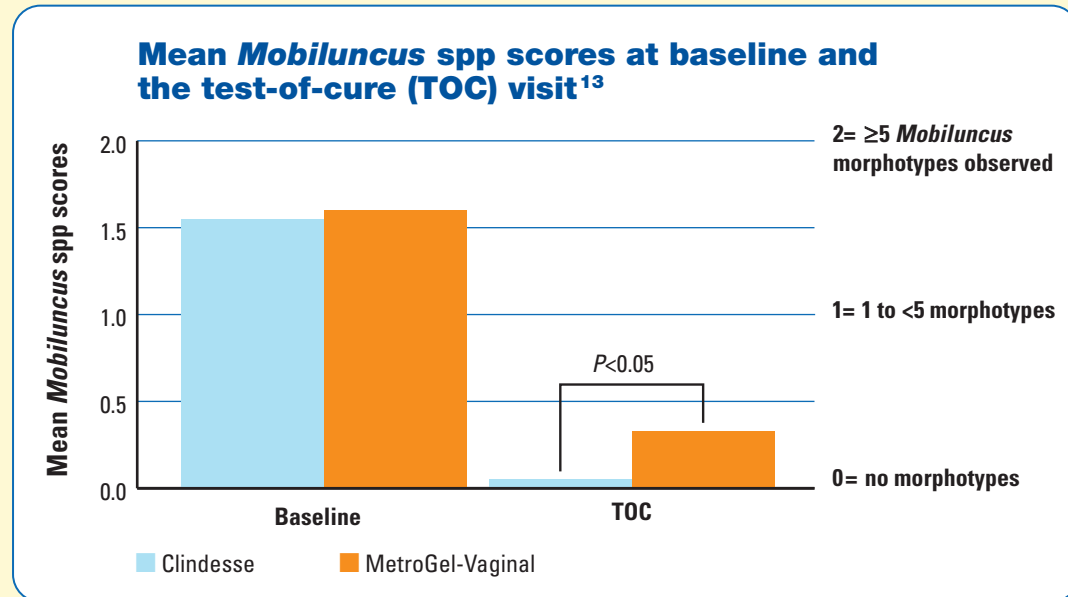
Clindesse® effectively drives away *Mobiluncus* spp

A single dose of Clindesse achieved better clearance of *Mobiluncus* morphotypes *in vivo* than 10 doses of MetroGel-Vaginal®¹³



Clindesse demonstrated a greater decrease in *Gardnerella vaginalis* scores than MetroGel-Vaginal in patients with *Mobiluncus* spp¹³

- The presence of *Mobiluncus* spp in patients with BV may have an effect on the ability of MetroGel-Vaginal to eradicate *Gardnerella vaginalis*¹³
 - This may lead to reduced initial antimicrobial activity and increased recurrence of infection¹³



"[Clindesse] reduces vaginal Mobiluncus morphotypes to a greater extent than [MetroGel-Vaginal] in patients with bacterial vaginosis; this correlates with a higher BV cure rate."
 —Nyirjesy P, et al. Sex Transm Dis. 2007;34:197-202.

- Clindesse demonstrated a significantly greater decrease in mean *Mobiluncus* spp scores than MetroGel-Vaginal at 21–30 days after the start of treatment (P < 0.05)¹³

Significantly more patients achieved microbiologic and clinical cure of BV with Clindesse than with MetroGel-Vaginal¹³

- *Mobiluncus* spp resistance, specifically to metronidazole, may play a role in recurrence, which occurs in up to 30% of women with BV¹³

||P=0.04 for both comparisons.



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Drive up patient satisfaction with Clindesse®



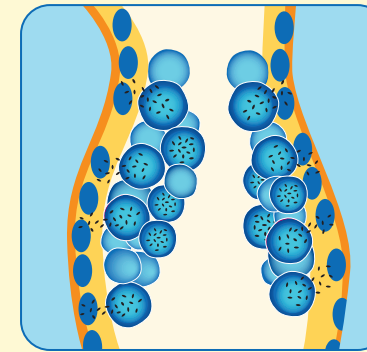
Clindesse offers efficacy and one-dose convenience for high patient satisfaction^{1,2}

- In a survey of more than 12,000 women, 97% said they would use Clindesse again¹⁰

What patients want from their BV therapy:	What patients get with Clindesse:
1. Single dose	✓
2. Symptom relief	✓
3. Less mess	✓
4. Anytime dosing	✓

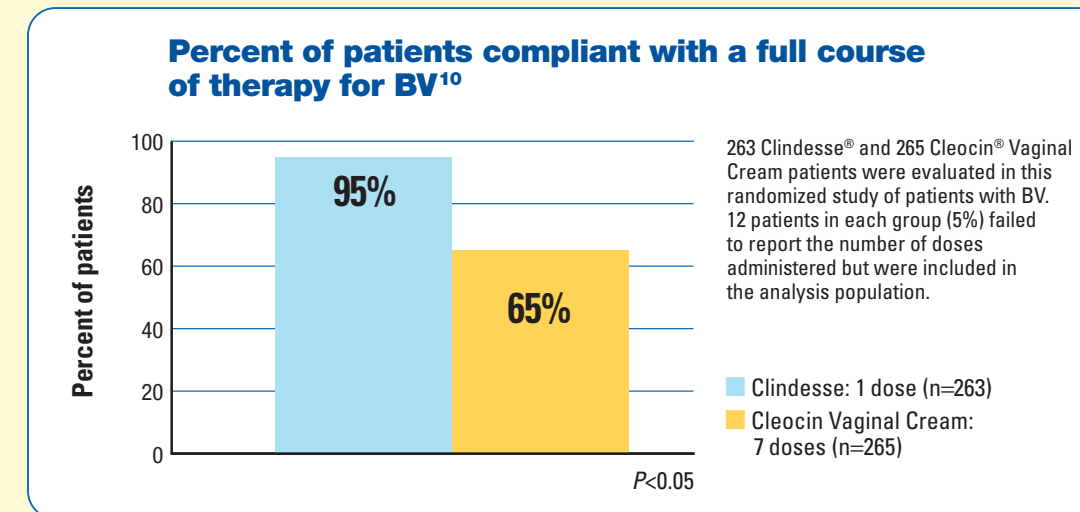
- Patients prefer the one-time dosing and fast relief of Clindesse^{2,10}
 - Clindesse is the **only** single-dose treatment approved for BV^{2,14,20-23}
 - In the same survey, almost all patients with symptoms experienced fast relief in less than 24 hours¹⁰

Clindesse has bioadhesion technology to provide proven effectiveness, single, anytime dosing, and minimal leakage^{1,2,24}



This unique bioadhesion delivery system is designed to adhere to wet living tissue, enabling Clindesse to stay in place for multiple days and targeted, continuous release of medication.²⁴

One-dose convenience and minimal leakage with Clindesse may enhance patient compliance



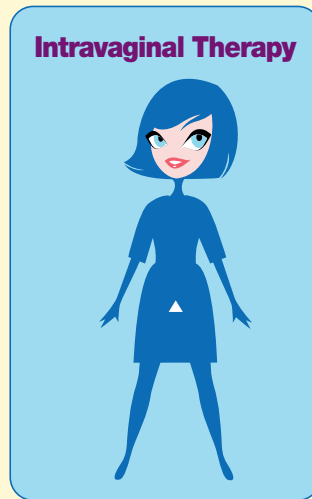
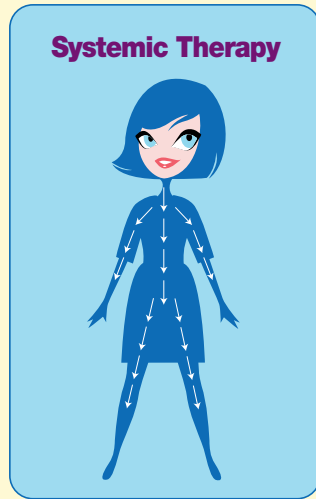
Cleocin® is a registered trademark of Pharmacia.



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Clindesse®—the BV therapy for patients who are on the go

Bioadhesion technology minimizes systemic absorption for a low incidence of adverse events even when compared with placebo^{2,10}



Clindesse is an intravaginal therapy that is locally absorbed and goes directly to the site of infection for safe, effective treatment.

- Clindesse is classified as Pregnancy Category B²
- Other BV products are classified as either Pregnancy Category B or C^{2,14,20-23}



For more information about Clindesse®, call us at 877-567-7676 or visit www.clindesse.com or www.ther-rx.com.



Important safety information for use of Clindesse:

This cream contains mineral oil that may weaken latex or rubber products such as condoms or vaginal contraceptive diaphragms. Therefore, the use of such barrier contraceptives is not recommended concurrently or for 5 days following treatment with Clindesse. During this time period, condoms may not be reliable for preventing pregnancy or for protecting against transmission of HIV and other sexually transmitted diseases.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including clindamycin. Orally and parenterally administered clindamycin has been associated with severe colitis. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of Clindesse, even though there is minimal systemic absorption of clindamycin from the vagina with administration of Clindesse Vaginal Cream.

In clinical trials (n=368), 1.6% of patients discontinued therapy due to adverse events. The most frequently reported adverse events were vaginosis fungal (14.1%), vulvovaginal pruritus (3.3%), and headache (2.7%).

References: 1. Faro S, Skokos CK. The efficacy and safety of a single dose of Clindesse™ vaginal cream versus a seven-dose regimen of Cleocin® vaginal cream in patients with bacterial vaginosis. *Infect Dis Obstet Gynecol.* 2005;13:155-160. 2. Clindesse® (clindamycin phosphate) Vaginal Cream prescribing information, Ther-Rx Corporation. 3. Wilson J. Managing recurrent bacterial vaginosis. *Sex Transm Infect.* 2004;80:8-11. 4. Kharsany ABM, Hoosen AA, Van den Ende J. Antimicrobial susceptibilities of *Gardnerella vaginalis*. *Antimicrob Agents Chemother.* 1993;37:2733-2735. 5. Ugwumadu A, Manyonda I, Reid F, Hay P. Effects of early oral clindamycin on late miscarriage and preterm delivery in asymptomatic women with abnormal vaginal flora and bacterial vaginosis: a randomised controlled trial. *Lancet.* 2003;361:983-988. 6. Puapermpoonsirt S, Watanabe K, Kato N, Ueno K. In vitro activities of 10 antimicrobial agents against bacterial vaginosis-associated anaerobic isolates from pregnant Japanese and Thai women. *Antimicrob Agents Chemother.* 1997;41:2297-2299. 7. Spiegel CA. Susceptibility of *Mobiluncus* species to 23 antimicrobial agents and 15 other compounds. *Antimicrob Agents Chemother.* 1987;31:249-252. 8. Ferris MJ, Masztal A, Aldridge KE, Fortenberry JD, Fidel PL Jr, Martin DH. Association of *Atopobium vaginae*, a recently described metronidazole resistant anaerobe, with bacterial vaginosis. *BMC Infect Dis.* 2004;4:5. 9. Burton JP, Chilcott CN, Al-Qumber M, et al. A preliminary survey of *Atopobium vaginae* in women attending the Dunedin gynaecology out-patients clinic: is the contribution of the hard-to-culture microbiota overlooked in gynaecological disorders? *Aust N Z J Obstet Gynaecol.* 2005;45:450-452. 10. Data on file, Ther-Rx Corporation. 11. Fredricks DN, Fiedler TL, Marrazzo JM. Molecular identification of bacteria associated with bacterial vaginosis. *N Engl J Med.* 2005;353:1899-1911. 12. Hillier S, Krohn MA, Watts DH, Wolner-Hanssen P, Eschenbach D. Microbiologic efficacy of intravaginal clindamycin cream for the treatment of bacterial vaginosis. *Obstet Gynecol.* 1990;76:407-413. 13. Nyirjesy P, McIntosh MJ, Steinmetz JI, Schumacher RJ, Joffrion JL. The effects of intravaginal clindamycin and metronidazole therapy on vaginal *Mobiluncus* morphotypes in patients with bacterial vaginosis. *Sex Transm Dis.* 2007;34:197-202. 14. MetroGel-Vaginal® (metronidazole vaginal gel) prescribing information, 3M Pharmaceuticals. 15. Verstraelen H, Verhelst R, Claeys G, Temmerman M, Vaneechoutte M. Culture-independent analysis of vaginal microflora: the unrecognized association of *Atopobium vaginae* with bacterial vaginosis. *Am J Obstet Gynecol.* 2004;191:1130-1132. 16. Austin MN, Meyn LA, Hillier SL. Susceptibility of vaginal bacteria to metronidazole and tinidazole. *Anaerobe.* 2006;12:227-230. 17. Nyirjesy P, McIntosh MJ, Gattermeir DJ, Schumacher RJ, Steinmetz JI, Joffrion JL. The effects of intravaginal clindamycin and metronidazole therapy on vaginal lactobacilli in patients with bacterial vaginosis. *Am J Obstet Gynecol.* 2006;194:1277-1282. 18. Centers for Disease Control and Prevention (CDC). Sexually transmitted diseases treatment guidelines. *MMWR Morb Mortal Wkly Rep.* 2006;55:1-94. 19. Gonzalez PAA, Ortiz ZMC, Irigoyen CA. Bacterial vaginosis: a "broad overview." *Rev Latinoam Microbiol.* 1999;41:25-34. 20. Cleocin® (clindamycin phosphate vaginal cream) prescribing information, Pharmacia & Upjohn Company. 21. Cleocin® Vaginal Ovules (clindamycin phosphate vaginal suppositories) prescribing information, Pharmacia & Upjohn Company. 22. Flagyl® ER (metronidazole extended release tablets) prescribing information, Pharmacia Corporation. 23. Tindamax® (tinidazole tablets) prescribing information, Mission® Pharmacal Company. 24. Merabet J, Thompson D, Levinson RS. Advancing vaginal drug delivery. *Expert Opin. Drug Deliv.* 2005;2:769-777.



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Clindesse® delivers efficacy and one-dose convenience for BV^{1,2}

	Clindesse® Vaginal Cream	MetroGel- Vaginal® Gel	Cleocin® Vaginal Cream and Vaginal Ovules	Flagyl® ER Tablets
Fast symptom relief ^{f10,14,20-22}	●			
One-dose convenience ^{2,14,20-22}	●			
No precautions against drinking alcohol ^{2,14,20-22}	●		●	
Pregnancy Category B ^{2,14,20-22}	●	●	●	●
Bioadhesive technology for less mess and anytime administration ^{2,14,20-22,24}	●			n/a
Convenient, prefilled applicator ^{2,14,20-22}	●			n/a

- In a survey of more than 12,000 women, 97% said they would use Clindesse again¹⁰

Flagyl® is a registered trademark of Pharmacia.



For demonstration purposes only. Not to be left with physician. Furnish full prescribing information.



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