Is medication adherence a challenge in your patients with Bacterial Vaginosis (BV)?



Now with NUVESSA® BV dosing can be...

One & Done[a]

[a]In a clinical study Nuvessa® demonstrated significantly higher cure rates over a vehicle gel.

Help your patients adhere to BV treatment[1] with NUVESSA® —

The one and only single-dose metronidazole vaginal gel (MVG) treatment for BV[2]



NUVESSA®
(metronidazole vaginal gel 1.3%)

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

NUVESSA® (metronidazole vaginal gel 1.3%) is an intravaginal treatment indicated for the treatment of bacterial vaginosis in females 12 years of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

NUVESSA is contraindicated in:

- Patients with a history of hypersensitivity to metronidazole, parabens, other ingredients of the formulation, or other nitroimidazole derivatives.
- Patients using disulfiram or within 2 weeks of disulfiram use.
- Patients using alcohol. Alcoholic preparations (e.g., ethanol, propylene glycol) and beverages should not be consumed during and for at least 24 hours after NUVESSA therapy.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

Prescribe NUVESSA® and deliver the assurance of the gold standard metronidazole in one targeted dose at bedtime.

Not all metronidazole-containing prescription products are the same[1]:

	NUVESSA®[2]	METROGEL®[3]	FLAGYL®[4]
Length of Treatment	● 1 day	● 5 days	● 7 days
Dosage Form	● 1 Prefilled Applicator	● Medicated gel + unfilled applicator(s)	● Oral tablets
Duration of Alcohol Restriction	● 24 hours[2]	● 5 days[3]	● 10 days[4]

When used as directed, a single bedtime dose of NUVESSA® avoids adherence issues associated with multi-dose treatments.[1]

Deliver efficacy with single-dose adherence

✔ Pre-filled applicator for her convenience[2]

✔ Lower systemic exposure (intravaginal administration results in 2-4% of the systemic exposure of a single, oral dose of metronidazole 500-mg oral tablets)[2]



IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS and PRECAUTIONS

Central and Peripheral Nervous System Effects

Convulsive seizures, encephalopathy, aseptic meningitis, optic and peripheral neuropathy have been reported in patients treated with oral or intravenous metronidazole. NUVESSA should be administered with caution to patients with central nervous system diseases. Discontinue promptly if abnormal neurologic signs development.

Carcinogenicity in Animals

Metronidazole has been shown to be carcinogenic at high doses administered orally in mice and rats. Unnecessary use of metronidazole should be avoided.

Drug/Laboratory Test Interactions

Metronidazole may interfere with certain serum chemistry values, such as aspartate aminotransferase (AST, SGOT), alanine aminotransferase (ALT, SGPT), lactate dehydrogenase (LDH), triglycerides, and glucose hexokinase. Values of zero may be observed.

Adverse Reactions

The most common adverse reactions (≥1%) observed in adult clinical studies were vulvovaginal candidiasis, headache, vulvovaginal pruritus, nausea, diarrhea, and dysmenorrhea.

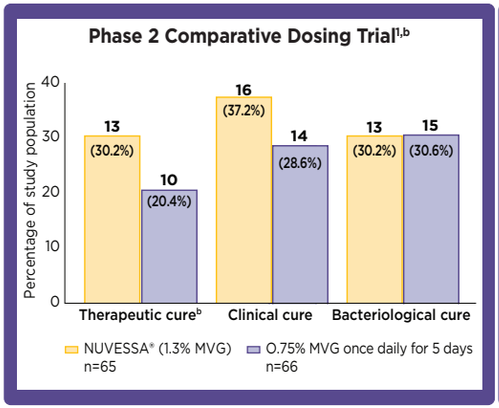
The most common adverse reactions (≥1%) observed in pediatric clinical studies was vulvovaginal discomfort.

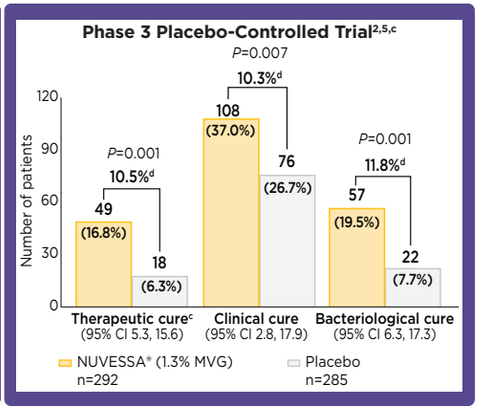
Why prescribe 5 doses when you can prescribe 1?

A 1-time dose at bedtime has been proven effective against bacterial vaginosis (BV)[1,5]

In a phase 2, randomized, controlled, investigator-blinded, dose-ranging study, women with BV (N=255) were treated with different metronidazole-based regimens. The primary endpoint was therapeutic cure (defined as clinical plus bacteriologic cure) at Day 21. A 1-time dose of MVG 1.3% at bedtime was equal in terms of safety, efficacy, and tolerability (see chart on left).[1]

In a phase 3, double-blind, vehicle-controlled clinical trial, the safety and efficacy of Nuvessa was evaluated in 577 subjects with a clinical diagnosis of BV. The primary endpoint was clinical cure at Day 21, defined as return of physiologic vaginal discharge, confirmed by the investigator with a negative whiff test and clue cells < 20% (with no pH criterion). See chart on right. Results are based on the modified intent-to-treat population.[5]





[b] Comparative statistics were not performed

The primary endpoint in this phase 2 study was therapeutic cure (defined as clinical plus bacteriologic cure) at Day 21.

Cure rates at test of cure/end of study: per-protocol[1]

[c] Bacterial vaginosis treatment in a randomized, double-blind, vehicle-controlled, parallel group study (N=577)

[d] Cure rate difference vs placebo.

Therapeutic cure: Resolution of both clinical signs and bacteriological markers of infection following treatment.

Clinical cure: Return to normal vaginal discharge, negative whiff test, and less than 20% clue cells on saline wet mount, as assessed by the investigator.

Bacteriological cure: Restoration of normal vaginal flora, defined as a Nugent score below 4.[1,5]

- At day 7 in Phase 3, Clinical Cure was achieved by a statistically significantly greater proportion of patients in the NUVESSA group vs. the vehicle gel group (41.1% vs. 20.0%). Bacteriological Cure was also achieved by a statistically significantly greater proportion of NUVESSA-treated patients vs. the Vehicle Gel group (33.9% vs. 6.3%).[2]
- There were no deaths or serious adverse reactions. Adverse reactions were reported by 19.0% of NUVESSA-treated subjects vs 16.1% of Vehicle Gel-treated subjects.[2,e]
  - Adverse reactions occurring in ≥1% of subjects receiving NUVESSA were: vulvovaginal candidiasis (5.6%), headache (2.2%), vulvovaginal pruritus (1.6%), nausea (1.6%), diarrhea (1.2%), and dysmenorrhea (1.2%). No subjects discontinued treatment due to adverse reactions.

[e] 321 non-pregnant females with a mean age of 33.4 years (range 18-67 years) received NUVESSA. Subjects administered a single dose of NUVESSA at bedtime on the first day of the study.

The Power of One

NUVESSA®

(metronidazole vaginal gel 1.3%)

Please see Important Safety Information throughout and accompanying full Prescribing Information.



Now with NUVESSA®
BV dosing can be...

One & Done

Help your patient adhere to BV treatment[1] with NUVESSA® — the one and only single-dose metronidazole vaginal gel (MVG) for BV

- ✔ *In a clinical study, a single dose of 1.3% MVG demonstrated comparable efficacy to a 5-dose regimen of 0.75% MVG[1]*
- ✔ *1 pre-filled applicator offers ease of use at bedtime[2]*
- ✔ *1 targeted dose at the site of infection minimizes unnecessary drug exposure[6]*

NUVESSA® Patient Savings Program

Visit: NUVESSA.COM

Text "NUVESSA" to 31700
for your patients who prefer to get the copay card on their mobile device.

Eligible patients may pay as little as $25[f] for their prescription

[f] The patient is responsible for the first $25 of their co-pay and cash-paying patients should pay approximately $55. For cash paying patients or insured patients when NUVESSA® is not covered by primary insurance, patients may still use this savings card but may have an outstanding balance. Please see Program Terms, Conditions, and Eligibility Criteria on back of savings card.



To ensure your patients receive NUVESSA®, add "Dispense as written"

Make sure your patients get the only single-dose, single-use metronidazole vaginal gel 1.3% treatment for BV

IMPORTANT SAFETY INFORMATION (cont'd)

Drug Interactions

Warfarin and other coumarin anticoagulants: Prolonged anticoagulant effects of warfarin and other coumarin anticoagulants have been reported with co-administration of oral metronidazole.

Elevated plasma lithium concentrations have been reported with oral metronidazole.

This is not a complete list of risks.

Please see attached full Prescribing Information for detailed information and online at Nuvessa.com.

References: 1. Chavoustie SE, et al. *J Low Genit Tract Dis.* 2015;19(2):129-134. **2.** Nuvessa® prescribing information. **3.** Metrogel® prescribing information. **4.** Flagyl® prescribing information. **5.** Schwebke JR, et al. *Sex Trans Dis.* 2015;42:376-381. **6.** Hirai J, et al. *J Infect Chemother.* 2025;31(11): 102826.

Please see Important Safety Information throughout and accompanying Prescribing Information which is also available on NUVESSA.COM

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