



Nuessa™ (metronidazole) – Expanded indication

- On August 3, 2018, the [FDA approved](#) Exeltis' [Nuessa \(metronidazole\)](#) vaginal gel 1.3%, for the treatment of bacterial vaginosis in females 12 years of age and older.
 - Previously, Nuessa was only approved for adult patients for the same indication.
- Metronidazole is also available generically as a [vaginal gel 0.75%](#), [topical cream 0.75%](#), [topical gel 0.75%](#), [topical gel 1%](#), [topical lotion 0.75%](#), [oral tablet](#), [oral capsule](#), and [injection](#),
 - Metronidazole vaginal gel 0.75% is indicated for the treatment of bacterial vaginosis.
 - Metronidazole topical cream, topical gel and topical lotion are indicated for the treatment of inflammatory papules and pustules of rosacea.
 - Metronidazole oral tablets, capsules and injection are indicated to treat a variety of infections. Refer to the individual drug labels for specific indications.
- The safety and efficacy of Nuessa have been established in pediatric patients between the ages of 12 and less than 18 years old.
 - Use of Nuessa in this age group is supported by evidence from a safety and tolerability study in 60 pediatric patients with bacterial vaginosis, and evidence from adequate and well-controlled studies in adult women.
- The most common adverse reaction ($\geq 1\%$) with Nuessa use in pediatric patients was vulvovaginal discomfort.
- The recommended dosage of Nuessa in all patients is a single-dose, pre-filled disposable applicator (which delivers approximately 5 g of gel containing 65 mg of metronidazole) administered once intravaginally at bedtime.
 - Nuessa is not for ophthalmic, dermal or oral use.



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