Ellage® Anhydrous Vaginal

A new base for compounded vaginal medications with prolonged beyond-use dates.

PCCA # **30-5110**

PCCA EXCLUSIVE

Ellage Anhydrous Vaginal is the first anhydrous base in pharmacy compounding developed specifically for vaginal applications. It is designed to be gentle on vaginal tissue, release drugs and maintain contact with the mucosa, all while providing a uniquely pleasant experience for patients with various health challenges who need compounded vaginal medication.

With water activity less than 0.6 (Aw < 0.6), Ellage is classified as an anhydrous vehicle, which allows pharmacy compounders to assign longer default beyond-use dates (BUDs) — without sacrificing performance or elegance.

Ellage Anhydrous Vaginal is made of pharmaceutical-grade ingredients and can accommodate a variety of drugs, including:

- Hormones
- Antimicrobials
- Antifungals
- Anti-inflammatories
- Anesthetics
- Vasodilators

This broad compatibility, combined with its gentle and nonirritating composition, means that Ellage is ideal in formulations for patients with a wide variety of vaginal conditions.

BENEFITS FOR COMPOUNDERS

- **Prolonged default BUDs**: Ellage is anhydrous, allowing preparations to have longer BUDs by default, which increases operational efficiency and saves compounders thousands of dollars in stability testing
- **Broad API compatibility**: Ellage is a stable, anhydrous vehicle appropriate for a variety of active pharmaceutical ingredients (APIs), including hormones, antimicrobials, antifungals, anti-inflammatories, anesthetics and vasodilators
- **Better patient compliance**: Ellage is nonirritating and has significant potential to minimize leakage, which may increase patient compliance

BENEFITS FOR PATIENTS

- **Potentially reduced leakage**: *In vitro* testing shows that Ellage has significant potential to minimize leakage of medication, offering a superior patient experience
- **No irritation**: Ellage is nonirritating and incredibly gentle on mucosal tissue, providing a pleasant base for customized vaginal medications

RELATED SPECIALTIES

- Gynecology
- Urology
- Family practice
- Internal medicine
- Functional medicine

Continued on the next page

Ellage® Anhydrous Vaginal

FORMULATED WITHOUT

- Wheat
- Milk
- Egg
- Soy
- Fish (including crustacean)
- Peanut
- Almond
- Pecan
- Macadamia
- Walnut
- Hazelnut
- Gluten

HOW DOES ELLAGE WORK?

Ellage Anhydrous Vaginal contains a self-emulsifying drug delivery system that creates a micro-emulsion when it comes in contact with water in vaginal fluid. This emulsion releases the active ingredients from the base to the mucosa. Once the active ingredients are released, the emulsifier system in the base also holds the drugs to the surface and increases the contact time. This combination of excellent drug release and adherence to mucosal tissue makes Ellage an ideal base for vaginal applications.

THE PROOF

The results of *in vitro* testing show that Ellage Anhydrous Vaginal releases drugs comparably to VersaBase® Cream, the industry standard for compounded vaginal medicine. The PCCA Science team has published studies showing how well it releases estriol and testosterone as well as amitriptyline and baclofen.[1,2]

Additional testing has shown that Ellage's self-emulsifying and mucoadhesive properties give it the potential to maximize drug solubility and bioavailability while increasing the contact time between APIs and vaginal tissue. Importantly, the base exhibited the ability to self-emulsify even in the presence of small amounts of simulated vaginal fluid, as might be expected with cases of vaginal dryness. PCCA Science has published two studies evaluating the base's self-emulsifying drug delivery system, one using a texture analyzer and one using a fluorescent dye.[3,4] They have published two studies testing its mucoadhesion as well, one employing traditional microscopic evaluation and one employing fluorescence microscopy.[5,6]

PCCA Science has also published in vitro studies showing that Ellage is nonirritating for vaginal tissue,[7,8] it does not affect vaginal pH,[9]* and it is likely to adhere to vaginal tissue for a long period of time without leakage or messiness despite regular vaginal secretions.[10]

FORMULATION EXAMPLES

- **PCCA Formula #13845**
  Estriol 0.1%/Testosterone 0.1% Vaginal (Ellage Anhydrous)
- **PCCA Formula #13944**
  Estriol/Estradiol [50%/50%] 0.5 mg/Gm Vaginal (Ellage Anhydrous)
- **PCCA Formula #13834**
  Amitriptyline HCl 2%/Baclofen 2% Vaginal (Ellage Anhydrous)
- **PCCA Formula #13849**
  Gabapentin 6% Vaginal (Ellage Anhydrous)
- **PCCA Formula #13860**
  Naltrexone HCl 0.5% Topical/Vaginal (Ellage Anhydrous)

For more example formulas, PCCA members can visit bit.ly/ellage-formulas.

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PCCA

Ellage® Anhydrous Vaginal

FREQUENTLY ASKED QUESTIONS

Does Ellage replace VersaBase Cream or MucoLox™/ VersaBase Gel for vaginal compounds?

While VersaBase Cream and the combination of MucoLox and VersaBase Gel are well established as options for vaginal compounds, Ellage Anhydrous Vaginal is a new anhydrous option to consider when starting a patient on a vaginal preparation. If a patient and her prescriber are pleased with her current compounded medication, however, we recommend not changing that compound.

Should pharmacy compounders transition patients who are using other bases to Ellage?

It depends on the situation. Ellage Anhydrous Vaginal is a great option when starting a new patient on a vaginal formulation. Also, if a patient is experiencing symptoms with her current medication, changing the base instead of the dose may be a good option, in which case this base is a consideration. However, if a patient and her prescriber are pleased with her current compounded medication, we recommend not changing that compound.

Which dispensing devices should pharmacy compounders use with Ellage?

The Topi-Click® Perl™ 35 mL Vaginal Dosing Kit (PCCA #35-5480) is our recommendation for dispensing preparations made with Ellage Anhydrous Vaginal. Our Exacta-Med oral/ topical syringes (0.5 mL to 10 mL) are options as dispensing devices too.

Does Ellage affect vaginal pH?

In vitro testing shows that Ellage Anhydrous Vaginal should not affect vaginal pH.[5] However, APIs and other ingredients that are incorporated into the base could potentially affect the pH.

REFERENCES

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** Ingredients that are incorporated into the base could potentially affect vaginal pH.*