

VersaBase[®] Anhydrous HRT

Patent-Pending Technology

A Topical Anhydrous Base for Female Hormone Delivery Allowing for Longer Default BUDs*

PCCA # 30-5056



For anhydrous formulations used in female hormone replacement therapy (HRT).

VersaBase Anhydrous HRT is the pharmacy compounding industry's first proprietary anhydrous topical base developed specifically to deliver female hormones through the skin. It is also the latest addition to the VersaBase family of compounding bases that has provided patients with much-needed customized medication options for over a decade. It uses a unique, patent-pending delivery system designed to improve the solubility of lipophilic molecules, such as hormones, and is proven to increase the permeation of those molecules into and through the skin. Despite this base being an anhydrous system, these lipophilic hormones are able to partition (release) from it and into the skin.

This base also addresses changes in the pharmacy compounding industry. Recent shifts in guidelines and standards have led to a focus on the role of water activity in establishing beyond-use dates (BUDs) for compounded medications. This, combined with the need of compounding pharmacies to maximize efficiency and control costs, is leading compounders to look for anhydrous bases to meet the needs of their patients while providing longer BUDs by default.

VersaBase Anhydrous HRT fulfills these needs. It has water activity below 0.6 ($A_w < 0.6$), which classifies it as an anhydrous base and allows for longer default BUDs according to the latest standards in pharmacy compounding. It performs exceptionally well in delivering female hormones through the skin, such as estriol, estradiol, progesterone and testosterone. It is also pleasing to the touch, offering patients elegant medications customized to their unique hormone replacement needs.

BENEFITS FOR COMPOUNDERS

- **Proven performance:** *In vitro* testing proves that VersaBase Anhydrous HRT delivers estriol, estradiol and progesterone into and through human skin tissue at a rate and extent that is better than, yet comparable to, VersaBase Cream (PCCA #30-3641)



- **Increased profitability:** It allows for longer default BUDs, which can save compounders thousands of dollars when compounding unique medications for individual patients
- **Increased efficiency:** Due to this base's solubilizing properties, most preparations made with it will not require milling, thus saving compounding and cleanup time

BENEFITS FOR PATIENTS

- **Convenience:** It's anhydrous, which allows for longer default BUDs and less-frequent prescription refills even if the medication hasn't undergone formal stability testing
- **Pleasant application:** It's smooth and creamy, and it rubs into the skin easily, offering a refined cosmetic feel to customized medications without a greasy or tacky residue

* According to standards established in the latest version of USP General Chapter 795.

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VersaBase[®] Anhydrous HRT



FORMULATED WITHOUT

- Water
- Soy
- Preservatives
- Nuts
- Petrolatum/mineral oil
- Gluten

RELATED SPECIALTIES

- Family practice
- Integrative medicine
- Internal medicine
- Endocrinology

FORMULATION EXAMPLES

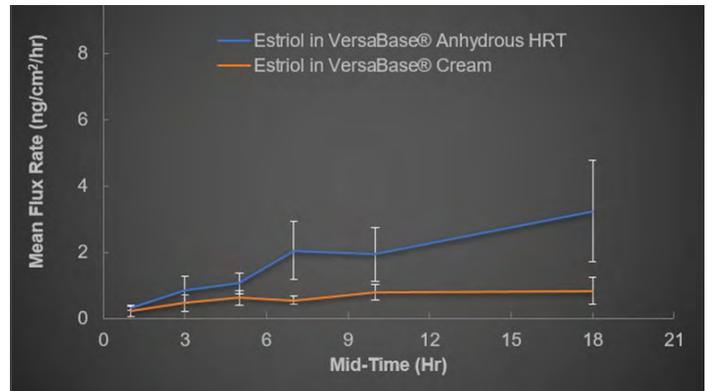
- **PCCA Formula #13756**
Progesterone 10 mg/Gm to 100 mg/Gm Topical Gel (VersaBase Anhydrous HRT) (FormulaPlus  BUD Bracketed Study)
- **PCCA Formula #13459**
Estriol/Estradiol [50%/50%] 0.25 mg/Gm to 5 mg/Gm Topical Gel (VersaBase Anhydrous HRT) (FormulaPlus  BUD Bracketed Study)
- **PCCA Formula #13499**
Estriol/Estradiol [80%/20%] 0.25 mg/Gm to 5 mg/Gm Topical Gel (VersaBase Anhydrous HRT) (FormulaPlus  BUD Bracketed Study)
- **PCCA Formula #13477**
Estriol/Estradiol [50%/50%] 1 mg/Gm/Progesterone 25 mg/Gm/Dehydroepiandrosterone 10 mg/Gm/Testosterone 1 mg/Gm Topical Gel (VersaBase Anhydrous HRT)
- **PCCA Formula #13469**
Testosterone 1 mg/Gm to 10 mg/Gm Topical Gel (VersaBase Anhydrous HRT) (FormulaPlus  BUD Bracketed Study)

For more example formulas, please visit bit.ly/versabasehrt.

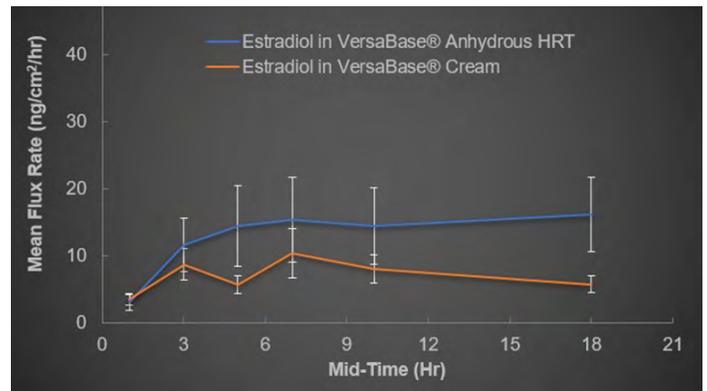
THE PROOF

The results of *in vitro* testing show that VersaBase Anhydrous HRT **delivered estriol, estradiol and progesterone through human skin tissue** at a higher rate and extent than, yet comparably to, VersaBase Cream, the industry standard for women's topical HRT compounds.

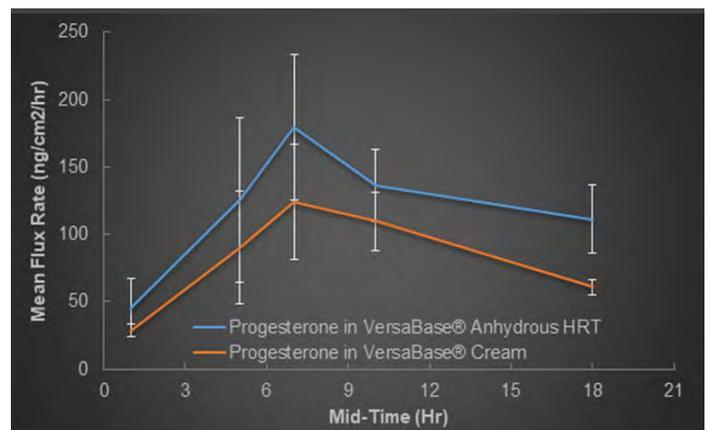
THE PROOF (Continued)



Absorption Rate of Estriol in VersaBase Anhydrous HRT vs. VersaBase Cream through ex Vivo Human Abdomen Skin over 18 Hours from a Single Application



Absorption Rate of Estradiol in VersaBase Anhydrous HRT vs. VersaBase Cream through ex Vivo Human Abdomen Skin over 18 Hours from a Single Application



Absorption Rate of Progesterone in VersaBase Anhydrous HRT vs. VersaBase Cream through ex Vivo Human Abdomen Skin over 18 Hours from a Single Application

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FREQUENTLY ASKED QUESTIONS

Does VersaBase Anhydrous HRT replace VersaBase Cream?

While this base does not replace VersaBase Cream, it is an anhydrous option to consider. VersaBase Anhydrous HRT is a great option when starting a new patient on an HRT preparation in light of the delivery data and low water activity properties.

Should I transition my patients who are using other topical bases for hormone replacement to this base?

It depends on the situation. VersaBase Anhydrous HRT is a great drug delivery option when starting a new patient on an HRT formulation. Also, if a patient is experiencing symptoms with her current HRT formulation, changing the base instead of the dose may be a good option, in which case this base is a consideration. However, changing a woman's hormone formulation may affect her hormone levels, thus affecting symptom control. Therefore, if a patient is currently stable on an HRT compound, and she and her prescriber are pleased with it, we recommend not changing that compound.

When transitioning a patient to this base from another topical base, should I use the same concentration of hormones?

Based on preliminary testing, VersaBase Anhydrous HRT delivers hormones at a rate and extent comparable to VersaBase Cream, so compounders may use an equivalent concentration when transitioning a patient from that base. However, since each patient is unique, the compounder may need to adjust the compound to suit the patient's needs based on the patient's response and consultation with the prescriber. When transitioning a patient from a topical base other than VersaBase Cream, the compounder should use their clinical judgment and consult the prescriber and available literature to determine dosing.

PLEASE NOTE

Always make sure you have checked the PCCA formula database and are following the most up-to-date version of a formula, as changes are continually made to existing formulations to provide the highest quality. The formulas and/or statements listed are provided for educational purposes only. They are compounding ideas that have commonly been requested by physicians and have not been evaluated by the Food and Drug Administration. Formulas and/or material listed are not to be interpreted as a promise, guarantee, or claim of therapeutic efficacy or safety. The information contained herein is not intended to replace or substitute for conventional medical care or encourage its abandonment. Every patient is unique, and formulas should be adjusted to meet their individual needs.

When transitioning a patient from another dosage form to a topical compound using this base, what adjustments should I make to the medication strength?

We do not recommend attempting to convert dosage strengths from one dosage form to another. Instead, it would be best to consider them separately. We recommend that the compounder use their clinical experience and consult the prescriber and available literature to determine an optimal starting dose for each patient.

Is VersaBase Anhydrous HRT recommended for vaginal use?

This base contains silicones that are not recommended for use on internal mucosal membranes (intra-vaginally or intra-rectally). Therefore, we recommend it for topical use only.

Do formulas using VersaBase Anhydrous HRT require the use of an ointment mill?

The majority of formulas we have tested and provided in the PCCA formulations database do not require milling, which greatly reduces total compounding time and cleanup. However, formulas with a high bulk powder load may still require milling. For such cases, please refer to PCCA formulas or do an initial small batch test of the preparation.

Which dispensing devices should I use with this base?

Topi-Click[®] metered topical applicators or EMP jars and topical syringes are options as dispensing devices to achieve the most accurate and reliable dosage with this base.

Due to the unique physical attributes (viscosity and rheology) of VersaBase Anhydrous HRT, we have found that MegaPumps[®], OptaPump™ and other airless dispensers do not provide accurate and uniform dosing with it. Therefore, we do not recommend using them as dispensing devices in this case.