

# PCCA Cream Bases Now Proven to Transport Progesterone Into and Through Human Skin

Performance Better Than Vanicream®

## Study:

### EVALUATION OF THE PERCUTANEOUS ABSORPTION OF PROGESTERONE, *IN VITRO*, USING THE HUMAN CADAVER SKIN MODEL

(Study performed by PRACS Institute, Ltd., an independent contract research facility.)

#### Summary

The study was designed to evaluate the percutaneous absorption pharmacokinetics of progesterone. Absorption was measured in human cadaver skin, *in vitro*, using the finite dose technique and Franz Diffusion Cells.

**Important Note:** This study should not be used as a means of determining dosing of progesterone topically. It is a study intended to evaluate the ability of certain cream vehicles to transport progesterone across a human skin sample, *in vitro*. It is not a substitute for *in vivo* pharmacokinetic studies. It also is important to note the formulations in this study are NOT rubbed into the skin, but simply applied to the skin via a pipette and left to diffuse.

#### Bases Tested

The bases used in the testing were: **VersaBase® Cream, Cosmetic HRT™**, a mixture of **VersaBase® Cream** and **VersaBase® Gel** (95% Cream/5% Gel) and the commercial cream **Vanicream®\***. The progesterone used was **Progesterone USP, PCCA Special Micronized**. Polyethylene glycol was used as a wetting agent at a concentration of 10%. The concentration of progesterone in each preparation was 50 mg/gm.

#### Study Skin Preparation

Percutaneous absorption was measured using the *in vitro* cadaver skin finite dose technique. Human cadaver trunk skin without obvious signs of skin disease, obtained within ~24 – 48 hours of death, was used in this study. It was dermatomed, prepared for cryo-preservation, sealed in a water impermeable plastic bag, and stored at ≤ -70° C until the day of the experiment. Prior to use it was thawed in ~37° C water, then rinsed in tap water to remove any adherent blood or other material from the surface.

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#### DONOR DEMOGRAPHICS

DONOR ID	AGE	RACE	SEX	INTEGRITY TEST RESULT <sup>1</sup>
DA100405	34	Caucasian	Male	0.24 ± 0.05
MM011907	48	Caucasian	Male	0.72 ± 0.22
BS120705	53	Caucasian	Male	0.54 ± 0.24

<sup>1</sup> Results are reported as µL-equ 3H:0; Acceptance ≤ 1.56 µL-equ/cm<sup>2</sup>

\* **Vanicream®** is a registered trademark of Pharmaceutical Specialties, Inc., Rochester, Minn.

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### Results

The data indicate that progesterone does penetrate into and through human skin, *in vitro*, from the test formulations evaluated in this study.

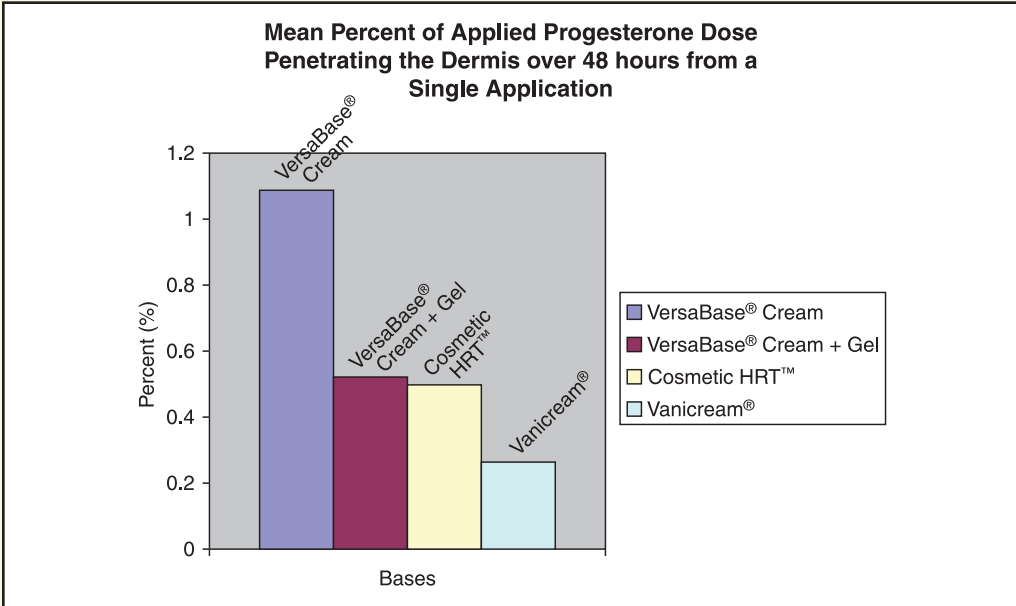
In general the penetration profile from all formulations is characterized by a rise in absorption to a peak at approximately 7 hours after dose application followed by a

slow decline in flux over time. A transient lower secondary peak of penetration is observed at approximately 28 hours after dose application at approximately half the flux than seen at the maximum.

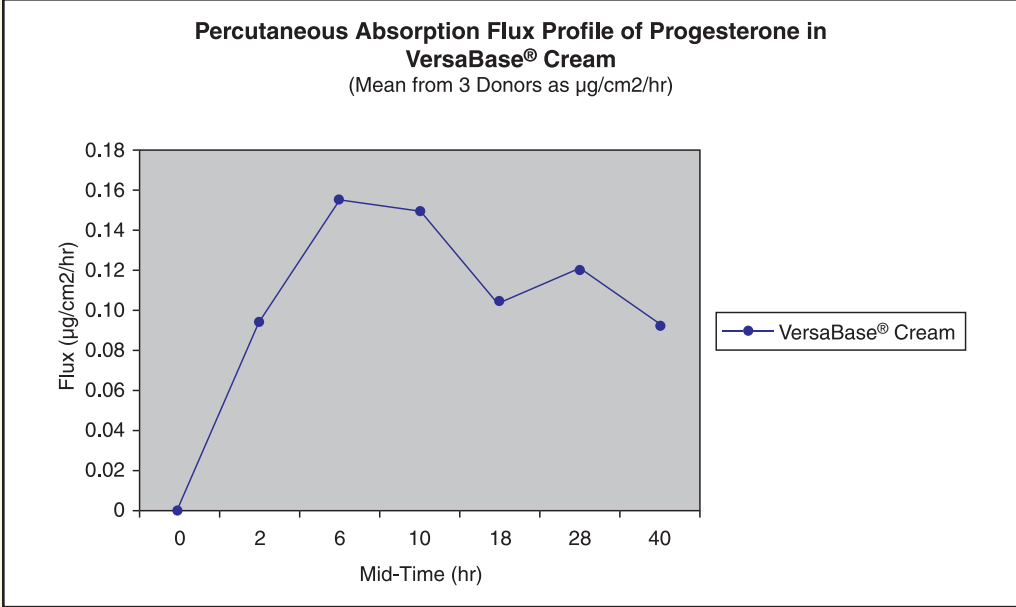
**When comparing the bases' abilities to transport progesterone deep into the dermis, VersaBase® Cream out-performed all bases, and delivered more than 4 times as much progesterone as the commercial base Vanicream®.**

### PCCA PRODUCT INFORMATION

- VersaBase® Cream ... PCCA #30-3641
- VersaBase® Gel..... PCCA #30-3656
- Cosmetic HRT™  
Base..... PCCA #30-3337
- Progesterone USP, PCCA Special  
Micronized ..... PCCA #30-3530



**VersaBase® Cream** delivered 4.07 times as much progesterone to the dermis as Vanicream®.



Peak flux of progesterone into receptor compartment at approximately 7 hours post application.

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