PCCA Lipoderm®

Patented Technology

A Validated Permeation-Enhancing Vehicle

PCCA # **30-3338**

PCCA EXCLUSIVE

The Standard in Permeation-Enhancing Bases

Lipoderm – the first proprietary permeation-enhancing vehicle in the compounding industry – is now included in the official USP Compounded Preparation Monograph for **Ondansetron Compounded Topical Gel (20 mg/mL)**.

Lipoderm is scientifically proven to deliver active pharmaceutical ingredients (APIs) through the skin,* and is supported by an ever-growing portfolio of peer-reviewed journal publications and FormulaPlus™ BUD-studied formulas. It is the ideal base in deep-penetrating topical formulations for local and systemic absorption of APIs. In fact, the patented Lipoderm core technology has also led to the development of an entire line of penetration-enhancing bases.

BENEFITS

- **Proven delivery.**
  Several studies published in peer-reviewed journals showed percutaneous absorption of a variety of APIs in Lipoderm, including four APIs at one time*
- **Increased quality, efficiency and convenience.**
  The most commonly requested Lipoderm formulations are backed by FormulaPlus BUD studies – which evaluate the chemical potency of a formula through forced degradation in a stability-indicating assay – increasing quality and efficiency for the compounder, and convenience for the patient
- **Physical stability.**
  It doesn't separate with refrigeration, resulting in cosmetically elegant and stable preparations
- **Better patient experience.**
  It's smooth, creamy and non-sticky, and it absorbs quickly
- **Non-comedogenic**

NOW INCLUDED IN OFFICIAL USP COMPOUNDED PREPARATION MONOGRAPH

RELATED SPECIALTIES

- Family practice
- Sports medicine
- Surgery
- Hospice
- Palliative care
- Oncology
- Men's health
- Podiatry
- Pediatrics
- Veterinary medicine

COMMONLY COMPOUNDED WITH

- NSAIDs
- Muscle relaxants
- Neuropathic APIs
- Anesthetics
- Anti-nausea APIs
- Sedatives
- Veterinary APIs
- Male hormones and hormone modulators

** See the Select Scientific Publications section of this document for published, peer-reviewed studies that show percutaneous absorption of APIs in Lipoderm.*

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FORMULATED WITHOUT
(Lipoderm & Lipoderm ActiveMax®)

- Almond
- Egg
- Fish
- Gluten
- Hazelnut
- Macadamia
- Milk
- Peanut
- Pecan
- Walnut

THE LIPODERM FAMILY

Lipoderm's patented core technology has led to the development of an entire line of permeation-enhancing bases, expanding your options for compounded transdermal and topical medications to address a variety of patients' needs.

- **Lipoderm** (PCCA #30-3338)
  For general permeation-enhancing and deep-penetrating topical formulations
- **Lipoderm ActiveMax** (PCCA #30-4482)
  For APIs in salt form at high concentrations
- **Lipoderm HMW™** (PCCA #30-4612)
  For APIs with high molecular weight
- **Anhydrous Lipoderm** (PCCA #30-4283)
  For APIs that are unstable in water

FORMULAS WITH FORMULAPLUS BEYOND-USE DATE (BUD) STUDIES

- **PCCA Formula #12373**
  Methimazole 2.5 mg/0.1 Gm to 10 mg/0.1 Gm Topical Lipoderm (Bracketed Study)
- **PCCA Formula #12375**
  Promethazine HCl 12.5 mg/Gm to 25 mg/Gm Topical Lipoderm (Bracketed Study)
- **PCCA Formula #9445**
  Benzocaine 20%/Lidocaine 6%/Tetracaine 4% Topical Lipoderm

FORMULAS WITH FORMULAPLUS BEYOND-USE DATE (BUD) STUDIES *(Continued)*

- **PCCA Formula #9872**
  Benzocaine 20%/Lidocaine 6%/Tetracaine 4%/DMSO 10% Topical Lipoderm
- **PCCA Formula #9447**
  Ibuprofen 20% Topical Lipoderm
- **PCCA Formula #10835**
  Ketamine HCl 5%/Gabapentin 10%/Clonidine HCl 0.2%/ Baclofen 2% Topical Lipoderm
- **PCCA Formula #9448**
  Ketoprofen 10% Topical Lipoderm
- **PCCA Formula #9492**
  Lorazepam 1 mg/Gm Topical Lipoderm
- **PCCA Formula #10863**
  Lorazepam 5 mg/Gm Topical Lipoderm
- **PCCA Formula #9494**
  Methylcobalamin 25 mg/Gm Topical Lipoderm
- **PCCA Formula #9875**
  Pentoxifylline 5%/Nifedipine 2% Topical Lipoderm
- **PCCA Formula #9450**
  Piroxicam 5% Topical Lipoderm
- **PCCA Formula #9491**
  Promethazine HCl 25 mg/Gm Topical Lipoderm
- **PCCA Formula #9452**
  Testosterone 5% (W/W) Topical Lipoderm
- **PCCA Formula #9732**
  Tramadol HCl 100 mg/Gm Topical Lipoderm
- **PCCA Formula #10672**
  Clomiphene Citrate 2.5% Topical Lipoderm ActiveMax
- **PCCA Formula #10673**
  Clomiphene Citrate 5% Topical Lipoderm ActiveMax

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FORMULAS WITH FORMULAPLUS BEYOND-USE DATE (BUD) STUDIES *(Continued)*

- **PCCA Formula #10287**
  Diclofenac Sodium 5%/Gabapentin 5%/Amitriptyline HCl 2% Topical Lipoderm ActiveMax
- **PCCA Formula #11090**
  Flurbiprofen 10%/Baclofen 2%/Cyclobenzaprine HCl 2%/ Tetracaine 2% Topical Lipoderm ActiveMax
- **PCCA Formula #11096**
  Ketoprofen 10%/Cyclobenzaprine HCl 2% Topical Lipoderm ActiveMax
- **PCCA Formula #10864**
  Lorazepam 5 mg/Gm Topical Lipoderm ActiveMax
- **PCCA Formula #10150**
  Promethazine HCl 125 mg/Gm Topical Lipoderm ActiveMax
- **PCCA Formula #12376**
  Trazodone HCl 100 mg/Gm Topical Lipoderm ActiveMax (Vet)

FREQUENTLY ASKED QUESTIONS

When should I consider using Lipoderm ActiveMax?
We recommend using Lipoderm ActiveMax when:

- A formula contains APIs that are in a salt form (e.g., Cl, Na), and are close to or exceed 15% of the total weight
  Note: We do NOT recommend using ActiveMax for non-salt form APIs
- The preparation liquefies or separates with the current formulation base
- The preparation is not thickening as expected, or if a thicker formula is desired
- Using higher concentrations of a single API in salt form

SELECT SCIENTIFIC PUBLICATIONS

1. Bassani, A. S., & Banov, D. (2016). Evaluation of the percutaneous absorption of ketamine HCl, gabapentin, clonidine HCl, and baclofen, in compounded transdermal pain formulations, using the Franz finite dose model. *Pain Medicine, 17*(2), 230-238. https://doi.org/10.1111/pme.12899*
2. Bassani, A. S., Banov, D., & Phan, H. (2015). *In vitro* characterization of the percutaneous absorption of lorazepam into human cadaver torso skin, using the Franz skin finite dose models. *Journal of Pharmaceutics & Drug Delivery Research, 4*(2). https://doi.org/10.4172/2325-9604.1000131
3. Bassani, A. S., Banov, D. & Phan, H. (2016). Characterization of the percutaneous absorption of ketoprofen using the Franz skin finite dose model. *Postgraduate Medicine, 128*(2), 262-267. http://dx.doi.org/10.1080/00325481.2016.1144448
4. Bassani, A. S., Banov, D., Simmons, C., & Phan, H. (2015). *In vitro* characterization of the percutaneous absorption of tramadol into inner ear domestic feline skin using the Franz skin finite dose model. *Veterinary Medicine and Animal Sciences, 3*(3). http://dx.doi.org/10.7243/2054-3425-3-3
5. Bassani, A. S., Banov, D., & Lehman, P. A. (2008). Evaluation of the percutaneous absorption of promethazine hydrochloride, *in vitro*, using the human ex vivo skin model. *International Journal of Pharmaceutical Compounding, 12*(3), 270-273. Retrieved from https://www.ijpc.com/
6. Branvold, A. & Carvalho, M. (2014). Pain management therapy: The benefits of compounded transdermal pain medication. *Journal of General Practice, 2*(6). http://dx.doi.org/10.4172/2329-9126.1000188

For more information on Lipoderm studies see PCCA Document #98391 or visit pccarx.com/science.

** Study also included Lipoderm ActiveMax*

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.