

## **MedLab Pharmacy**

The Compounding Experts™

Telephone: 954-400-0560 medlabpharmacy@gmail.com Fax To: 954-606-5260

## PRESCRIBER UPDATE: New BioMax™ Dosage Forms

## **Sublingual Tablets & Transdermal Gels**



## MedLab Pharmacy, Inc.

7300 W. McNab Road, Suite 112, Tamarac, Florida 33321

Tel: 954-400-0560 Fax: 954-606-5260

Email: medlabpharmacy@gmail.com

Copyright© 2017-2019 - Dr. Alan C. Zimmer, Pharmacist, Compounding Specialist - All Rights Reserved.

No part of this document may be reproduced, distributed, or transmitted by any means, including photocopying, recording, electronic or mechanical methods, without prior request and written permission. Infringers may be liable for *damages including back-dated royalties*.

### **MedLab Pharmacy: The Compounding Experts**

**BioMax™ Enhanced Preparations: MedLab Patients Feel the Difference!!!** 

In an industry that has evolved continuously over decades, MedLab Pharmacy has made it our mission to develop and continuously provide leading evidence-based preparations. Patients feel the advantages of our BioMax™ Enhanced-Preparations. We dedicate ourselves each day to accomplishing this mission.

#### **OUR FOCUS: Purity, Potency, Innovation, Experience, and Talent**

At MedLab Pharmacy, getting top results for our patients is our greatest asset. We are committed to providing excellence, innovation, and above average patient care. So, where do we stand in regards to standards, regulations, and compliance?

- We meet and strive to exceed regulations established by our State Board of Pharmacy, the FDA, and the DEA. All requirements listed in the United States Pharmacopeia for compounding are strictly followed.
- All our BioMax™ Enhanced-Preparations undergo ongoing analytical testing for potency and stability conducted by top outside laboratories that are fully registered and licensed in the USA.
- All our formulations and compounding procedures are written, reviewed, and approved by highly accomplished experts in the field working for the most reputable companies in the industry.
- All prescription orders go through a multi-check system to ensure compliance with all required laws, regulations, and standards of practice protocols.
- We follow standards for continuous quality improvement to assure that we are continuously monitoring and improving our processes and outcome measures.
- We purchase all our pharmaceutical ingredients from the largest and most reputable FDA approved facilities nationwide. Each ingredient contains an official certificate of analysis which is checked, verified, and entered into our database to ensure proper compliance and continuous monitoring.
- All our pharmaceutical ingredients are properly stored to ensure shelf-life, potency and stability.

Our Registered Pharmacists and Certified Pharmacy Technicians go through extensive training in the preparation, dispensing, and quality assurance of all our BioMax™ Enhanced Compounded Preparations.

#### MESSAGE FROM THE AUTHOR

Dr. Alan C. Zimmer, Pharmacist, Compounding Specialist - "MedLab Pharmacy, Inc. is on the forefront of finding new ways to improve the quality of pharmaceutical care delivered to patients. Our new BioMax™ Delivery System Technology is designed to maximize the pharmacological benefits of every preparation. "By keeping prescribers and their staff up-to-date, they are better able to select the most appropriate treatment options for their patients, along with optimized routes of administration and individualized patient specific dosing." As a result of scientific advances, we pioneered BioMax™ pharmacokinetically optimized preparations, and are now better able to offer patient's new and expanded treatment options. We are leading experts in the field of compounding, and are extremely dedicated toward providing innovative ways to improve the health of every patient we serve."

### **INDEX OF PAGES**

- 1. MedLab: The Compounding Experts (Page 2)
- 2. Notice to Readers (Page 4)
- 3. BioMax™ Compound Drug Breakthroughs (Page 5)
- 4. Index of Therapeutic Applications (Page 6)
- 5. BioMax™ Delivery System Benefits (Page 7)
- 6. BioMax™ Dosage Forms (Page 8)
- 7. The BioMax™ Advantage (Page 9)
- 8. MedLab: A Team of Talent (Page 11)
- 9. Auto-Ship Savings Program (Page 12)
- 10. Pricing Table (Page 14)
- 11. Delivery Instructions (Page 15)
- 12. Sublingual's & Transdermals (Page 16)

#### **Notices to Readers**

BioMax™ Lecture Series: The information contained within this document is derived from MedLab Pharmacy's lecture notes on BioMax© Enhanced-Preparations and Delivery Systems. It is presented as such, and should not be interpreted as official labeling, or approved prescribing information. Any prescription order to treat a medical condition in a patient must be based on a patient's clinical presentation, exam findings, laboratory testing, the prescriber's professional experience, and ongoing clinical monitoring by an experienced healthcare professional currently licensed to prescribe prescription medications under state and federal law.

<u>Customizations</u> – Prescription Compounding is the art and science of mixing customized dosage forms. Prescriber's may customize <u>all</u> formulations listed in our Master Formulary to better meet the needs of individual patients.

<u>Fax Ordering of a Controlled Substance</u>: After receiving a prescription for a prescription compound containing a CIII or CIV controlled substance, a Registered Pharmacist will follow-up with a telephone call to the prescriber to further authorize it as a verbal order, and immediately reduce it to writing in compliance with the rules and regulations of the Florida State Board of Pharmacy.

<u>Disclaimer</u>: The information provided herein is for reference only and is not to be relied upon as making any representation or decision as to the safety and efficacy of any compounded drug preparation. Nothing herein is intended to replace or influence the independent judgment of a healthcare professional trained and licensed to prescribe prescription medications in the State of Florida.

<u>Copyright & Trademark Notice</u>: The contents of this document are protected under Intellectual Property law. No part of this document may be reproduced, distributed, or transmitted by any means, including photocopying, recording, electronic or mechanical methods, for commercial usage outside of the author's normal course of business as a compounding pharmacy without prior request and written permission, which will most likely be negotiated and granted to assist in the pharmaceutical care of an individual or groups of patients. Plagiarizers and infringers, who ignore this statement without prior consent of MedLab Pharmacy Inc., may be liable for damages including back-dated royalties.

# BioMax™ Compound Drug Breakthroughs Synergistic / Kinetics / Dynamics

#### **BIOMAX DEFINATION:**

BioMax™ Compound Drug Preparations all contain synergistic mixtures of FDA approved active pharmaceutical ingredients, compounded together into optimized dosage forms; all designed to maximize the potential of their mechanisms of action and pharmacokinetic properties, including the absorption, distribution, metabolism, and elimination of each ingredient from the body.

#### **INDEX OF THERAPEUTIC APPLICATIONS:**

- Alzheimers-Parkinsons
- Acute & Chronic Pain Relief
- Addition Disorders
- Allergies & Asthma
- Anti-Aging Medicine
- Age-Reversal Medicine
- Autoimmune Function (LDN)
- Chronic Sinusitis
- COPD
- Diabetes Medicine
- Growth Hormone Balancing
- Hair-Regrowth (Men & Women)
- Male Testosterone Balancing

- Migraine Headaches
- Rheumatology
- Sexual Dysfunction
- Skin Disorders
- Sleep and Anxiety
- Smoking Cessation (Nicotine Relief)
- Total Body Detox
- Thyroid Hormone Balancing (Natural)
- Nutraceuticals
- Weight-Loss
- Women's Hormone Balancing
- Vertigo/TravelSickness
- Veterinary

## **NEW BIOMAX™ DRUG DELIVERY SYSTEMS**

#### A Major Advance in Compound Drug Therapies

#### Summary Of BioMax™ Formulation Benefits

Major advances have been made in the development of new compound treatment options for general and specialty medicine. The therapeutic effects of all of these medications are dependent on the technical aspects of the delivery system used to introduce active ingredients into the body.

As a result of our new (proprietary) **BioMax™ Deliver System Technology** many new treatment options are now available for a broad spectrum of health conditions including: sexual dysfunction, weight-loss, body composition (fat-loss, muscle gain), autoimmune and inflammatory disorders, migraine headaches, nausea and vomiting, anti-aging medicine, sleep medicine, hair-loss, acute and chronic pain, arthritis and bursitis, neuropathies, and nerve pain.

By maximizing the rate and extent of absorption through formulation enhancements and innovative route of administration alterations, the delivery of each active ingredient in their original molecular configuration (unchanged, non-metabolized forms) can occur faster, and reach important receptor sites in greater concentrations, where dramatic improvements in therapeutic effects can occur and patients can experience real benefits.

#### BioMax™ Preparations – The 5 Major Advances

- 1. Maximizes Bioavailability of Active Ingredients
- 2. Maximizes Delivery of Parent Unchanged Molecules
- 3. Delivers a Much Faster Direct Onset of Pharmacological Effects
- 4. Minimizes Potential Side-Effects of Drug Administration
- 5. Minimizes Overall Treatment Costs for Patients

Copyright© 2017-2018 - MedLab Pharmacy, Inc. - All Rights Reserved

## **BioMax™ Delivery System Technology**

Our proprietary BioMax™ Deliver System Technology is designed to maximize the therapeutic benefits of prescription preparations, minimize side-effects, and reduce overall treatment costs for patients.

By maximizing the rate and extent of absorption through formulation enhancements and strategic route of administration alterations, the delivery of active ingredients in their original molecular configuration (unchanged, non-metabolized forms) can occur faster, and reach important receptor sites in greater concentrations.

To achieve the many advantages of BioMax™ Enhanced Preparations, each formulation is based on the latest advances in delivery system technology.

## BioMax™ Dosage Forms are Based On:

- The Latest Evidence-Based Research and Development
- Advanced Base Formulations and Proprietary Ratio's
- Particle Size Manipulation & Micronization Techniques
- Advanced Techniques to Optimize Pharmacokinetic Parameters

All BioMax<sup>™</sup> Preparations are **evidence-based** formulations. Their development is based on both clinical and analytical scientific studies, and decades of anecdotal results reported by patients and practioners during regular prescription usage written by licensed prescribers in non-controlled patient populations.

BioMax<sup>™</sup> formulations are state-or-the-art pharmaceutically elegant preparations that are highly desirable for patient use and deliver exact dosing in user-friendly packaging.

## **THE BioMax™ ADVANTAGE**

#### Pharmacokinetically Optimized Preparations

**Pharmacology** is broken down into two distinctly different clinical sciences know as **Pharmacodynamics** and **Pharmacokinetics**.

**Pharmacodynamics** establishes a drugs <u>mechanism of action</u>. A drugs **mechanism of action** simply means how it works in the body. A drugs molecular configuration determines how it will trigger targeted receptor sites throughout the body.

**Pharmacokinetics** details the movement of a drug throughout the body over time. Its acronym **ADME** defines movement in terms of <u>Absorption</u>, <u>Distribution</u>, <u>Metabolism</u>, and <u>Elimination</u>.

The pharmacokinetic properties of a drug are dependent on the <u>delivery system</u> used to introduce it into the body. The important components of a delivery system include its formulation ingredients, mixing process, dosage form and route of administration.

**BioMax™** Enhanced Preparations focus on proprietary methods to optimize the pharmacokinetic properties of a drug which include its absorption, distribution, and metabolism so that it may reach its full pharmacodynamic potential, and its resulting therapeutic effects.

BioMax™ Sublingual Tablets, BioMax™ Transdermal Gels, and BioMax™ Hair-Growth Solutions are all specifically designed to maximize the rate and extent of absorption of the active ingredients contained in each dosage form.

By introducing <u>unchanged</u>, <u>non-metabolized</u>, <u>parent molecules</u> directly into the blood stream with no first-pass effect using our **BioMax™ Sublingual Tablets**, or by penetrating the skin deep enough to reach distant receptor sites using our **BioMax™ Transdermal Gels**, or enhancing it distribution deep into hair follicles using our **BioMax™ Hair-Growth Solutions**, are all ways we work to optimize a drugs pharmacokinetic properties in **BioMax™ Formulations**.

In addition, **BioMax™** Enhanced Preparations can all be customized to better meet the needs of individual patients and not the one size fits all approach typical of commercial products.

Many BioMax<sup>™</sup> Formulations contain <u>more than one drug</u> with <u>complementary mechanisms of actions</u> to treat medical disorders according to more complex treatment protocols.

By doing this, **BioMax™ Preparations** can <u>simplify</u> a patient's medication regimen, and thus **increase patient compliance** which is a critical component of effective drug therapy and treatment success.

## **BioMax™ Enhanced Dosage Forms**

#### **BioMax™ Sublingual Tablets**

- The pharmaceutical industry's most under-utilized dosage form
- Disintegrates under the tongue in seconds
- Increases bioavailability dramatically
- Onset of pharmacological effects occurs in minutes.
- Avoids first-pass metabolism, avoids toxic formation of early first-pass metabolites.
- Delivers unchanged, non-metabolized, parent molecules directly into the bloodstream.

#### **BioMax™ Transdermal Gels**

- A true transdermal delivery system.
- Enables greater amounts of active ingredients to be effective in the formulation.
- Trillions of micelles with active polar heads force encapsulation of active ingredients.
- Delivers active pharmaceutical ingredients directly to distant receptor sites in tissues.
- Circumvents almost all gastrointestinal side effects found in oral dosage forms.
- Enables long-term NSAID therapy in patients at risk for ulceration from oral therapy.

#### **BioMax™ Topical Hair Liquid**

- Enables the addition of much higher amounts of Minoxidil and other ingredients.
- Enhances the even spread of hair liquid around the scalp.
- Allows deep penetration of active ingredients into the hair follicles.
- Convenient spray bottles make it simple to enhance long-term compliance.

# MedLab Pharmacy: A Team of Talent The Compounding Experts™

- American Corporation, American Quality, American Pride and Excellence
- Florida State Board of Pharmacy licensed and inspected facility
- Run by a team of results driven professionals with Doctorate Degrees
- State-of-the Art professional compounding facility
- Clean, well-kept, organized, exceeds professional healthcare standards
- Innovative treatments options for state-of-the-art patient care
- Professional delivery of all preparations, including those requiring cold cooler packaging, to patients at home, work, or at another location.
- Low-cost pricing plus auto-ship savings make it more affordable for patients
- Auto-Ship Program further reduces cost and enhances compliance, patients receive their medications before they run out
- Specially trained Pharmacists available for patient education and to answer questions
- Physician consultants: rounds to doctor's offices to keep prescribers up-to-date
- All preparations are dispensed with proprietary Patient Medication Guides which list the active ingredients, packaging instructions, administration instructions, storage instructions, emergency instructions, warnings, precautions, special instructions, and potential adverse reactions.
- Proprietary BioMax™ Delivery System Technology improves treatment results
- Innovative treatment options provide unique solutions to improve patient care

## **AUTO-SHIP SAVINGS PROGRAM**

## **Major Benefits**

- 1. Enhances patient compliance with dosage regimens
- 2. Provides real cost-savings on initial prescriptions and every refill thereafter.
- 3. Patients receive their medication one week prior to their run-out-date.

Pharmaceutical compounding is the art and science of creating customized medication dosage forms to better meet the specific needs of individual patients. Being able to anticipate the workload a week in advance can reduce our costs dramatically

In addition to ingredient costs, other significant expenses that are involved in compounding are: random testing of compounded mixtures by a third party analytical laboratory to confirm potency, purity and stability, the time required for a Registered Pharmacist to produce compounded mixtures, the equipment time and expense needed to produce customized dosage forms, and the extensive clean-up procedures that must be followed after completion of every batch mixture completed.

#### **Auto-Ship Makes the Cost of Prescription Medication More Affordable!**

BioMax™ Preparations are all compounded fresh prior to dispensing to ensure maximum potency and stability, before beyond-use-dates, expiration dates, and discard dates are assigned. If we are able to create larger batches of the exact same medication at a time it reduces our total costs dramatically.

#### We Pass These Saving Onto Our Patients!

With the approval of the prescriber, we can pass these savings onto patients who choose to have their prescriptions placed on Auto-Ship based on the day's supply for them to receive their medications one week prior to their run-out-date.

Auto-Ship may **increase patient's compliance** by overcoming the problem that occurs when patients forget to reorder on time and run out of medications. All preparations scheduled on Auto-Ship cycles reach the patient <u>one week prior to their run-out date</u>.

## **INSTRUCTIONS FOR AUTO-SHIP PROGRAM**

- 1. The prescriber must authorize refills on the original prescription.
- 2. The patient must authorize their prescription to be placed on Auto-Ship during a recorded telephone call from the pharmacy for quality assurance.
- 3. The patient must select how often they want to receive their medication delivery based on an appropriate days supply cycle.
- 4. All refills placed on Auto-Ship will be delivered one-week prior to the patients run-out date to enable continued compliance with their dosage regimen.
- 5. All refills are ultimately controlled by the <u>prescriber</u> as indicated by the number of refills authorized on the original prescription, and the patients authorized delivery schedule based on their usage needs and consent for ongoing automatic shipments.

Auto-Ship may be discontinued by the prescriber or the patient at any time, without any financial penalty or additional expense, either in writing or verbally over the phone which will be recorded for quality assurance purposes.

The patient may cancel and the prescriber may discontinue any medication from being refilled on the auto-ship program, prior to the next shipment being sent, without any financial penalty or further payment.

<u>AUTO-SHIP CANCELLATION POLICY</u>: a patient or prescriber may remove a prescription from Auto-Ship status with a simple telephone call to the pharmacy or by fax, email, or in-person at the pharmacy. The Auto-Ship status will be removed immediately, and no further Auto-Ship deliveries will continue thereafter.

## **PRICING TABLE: Compound Drugs**

All Compounds Qualify for Both Auto-Ship Discounts And 90 Day Supply Discounts	
Compounding Fee (See Auto-Ship Discount Below)	\$59 (30 Days Supply)
*** (Minus \$30 Auto-Ship Discount)	- <b>\$30</b> (\$29 Compd'ing fee)
*Most Ingredients	\$20 each (30 days supply)
* (Minus 25% Ingredient Discount for 90 day supplies)	- <b>25</b> % (off all Ingredients)
Controlled Substances (Ingredients)	Add \$20 (one-time fee)
Refrigerated Substances (Ingredients)	Add \$20 (one-time fee)
PLEASE ADD A ONE-TIME FEE FOR HANDLING, & TAMPER RESISTANT PAGE	
Shipping (Room Temperature + Tamper Resistant)	\$12.50 (Flat Rate)
Shipping (Ice Packed Cooler + Tamper Resistant)	\$22.50 (Flat Rate)

<sup>\*</sup>Please Note: Expensive ingredients over \$20 require a custom quote.

## **DELIVERY INSTRUCTIONS**

#### **ALL ORDERS ARE SHIPPED FOR NEXT-DAY DELIVERY**

(In remote locations USPS/UPS delivery may take 2 days.)

The Price of a custom preparation must be obtained <u>after</u> the prescription is received so it can be calculated accurately at that time of the order and quoted to the patient before the preparation is compounded and shipped.

#### **AUTO-SHIP PROGRAM BENEFITS**

In addition to receiving VIP discounted batch pricing, the purpose of our Auto-Ship Program is to provide a convenient way for patients to stay compliant with their dosage regimens.

All Auto-Ship orders are batched and shipped on a weekly basis according to their cycle fill dates. Patients must designate how often they want to receive their preparations so they arrive one week before their run out date.

When prescriptions placed on Auto-Ship run out of refills, prescribers and patients are notified ahead of time, so patients can stay compliant with their dosage regimens before their medications run out.

#### PACKAGING AND SHIPPING COSTS

- 1. Cost for Room-Temperature Tamper-Resistant Packaging with Shipping: \$12.50
- 2. Cost for Cooler Plus Frozen Ice-Packs in Tamper-Resistant Packaging with Shipping: \$22.50

#### **WORLD'S BEST FORMULATIONS**



## MedLab Pharmacy

COMPOUND DRUG DESK REFERENCE

#### **NEW BIOMAX™ SUBLINGUAL TABLETS**

- The pharmaceutical industry's <u>most under-utilized dosage form</u> with so many "<u>major benefits</u>" now available for treating patients.
- Disintegrates under the tongue in seconds.
- Fully absorbed in minutes, faster peak concentration of medicines in the bloodstream.
- May be used as an option <u>instead</u> of certain injectable drugs.
- Avoids First-Pass Metabolism by the liver.
- Delivers non-metabolized (unchanged) parent molecules into the blood-stream.
- Maximizes the bioavailabilty of many drugs that breakdown in the gastrointestinal tract.
- Optimizes the rate and extent of absorption of many medications versus oral administration.
- More <u>convenient</u> when <u>away</u> from home, just place under tongue, no liquids to swallow.
- May reduce or eliminate gastrointestinal side effects from oral medications.
- Faster-Acting for unexpected events, unplanned events, and acute events.

#### **NEW BIOMAX™ TRANSDERMAL GELS - PUMP BOTTLES**

#### Penetrates Deeper Than Previous Over-Priced Creams

- A TRUE Transdermal Delivery System: State-of-the-Art for multiple high-potency ingredients.
- Active ingredients are mixed with pharmaceutical penetration enhancers.
- Micellization processes encapsulate active ingredients into trillions of micro-spears.
- Transdermal dosage form induces ingredients to diffuse across important skin layers.
- Trillions of micelles with polar heads diffuse drugs across skin barriers much faster.
- Forces greater amounts of drug molecules to permeate deeper down below the skin.
- Delivers active pharmaceutical ingredients into more distant tissues.
- Medications exert their pharmacological properties directly at their receptor sites.
- Eliminates almost all gastrointestinal side effects from oral anti-inflammatory drugs.
- Enables many patients with prior ulcerations from oral NSAIDS to receive treatment.

#### MedLab Pharmacy, Inc.

World's Best Formulations / Lowest Prices Nationwide

7300 W. McNab Road, Ste 112, Tamarac, FL 33321 Tel: 954-400-0560 · Fax To: 954-606-5260