#### LIPIGESIC M- feverfew and ginger gel PuraMed BioScience, Inc.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

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#### What is a Migraine?

Migraines are classified as "benign headaches" because they are not caused by an underlying medical condition such as a tumor, aneurysm or a similar medical disorder. But, migraine is far from "benign" in terms of its impact on the individual and those around them.

The pain of a migraine headache is often described as an intense pulsing, throbbing and sometimes disabling pain, which may be limited to one side of the head. It may be accompanied by sensitivity to light and sound, nausea and vomiting.

There are two major types of migraine headache: classic and common. Classic migraines are often signaled by "aura," a visual sensory illusion, such as jagged bands of light obscuring vision, or shimmering lights around the edges of objects, before the actual pain begins. Only about 20 percent of sufferers experience aura. Common migraines occur without aura.

Migraine headaches may result from dietary, environmental and lifestyle triggers. Most migraines are not caused by a single identifiable source, and a person's response to a trigger varies from occurrence to occurrence.

#### **Migraine Triggers**

#### DIETARY TRIGGERS

Alcoholic drinks (esp. red wine) Changes in caffeine intake Aged cheese Chocolate Monosodium glutamate (MSG) Nitrates (food preservatives) Yeast Smoked fish Nuts Pickled foods Missed meals

#### ENVIRONMENTAL TRIGGERS

Weather or altitude changes Bright lights including sunlight Noise sensitivity Sensitivity to strong odors Complex visual patterns Travel

# LIFESTYLE TRIGGERS

Changes in sleep routine Overuse of headache medicines Hormones – women suffer from migraines 3:1 over men Stress, depression, anxiety, emotions

# What will LipiGesic<sup>™</sup>-M do for me?

LipiGesic-M is a non-prescription sublingual (under-the-tongue) formulation of natural ingredients used in the early stages of onset to relieve the pain and reduce the associated symptoms of migraine – nausea, vomiting, and sensitivity to light and sound.



In a double-blind placebo controlled study, 64% of headaches resolved with no pain or only mild pain, within 2 hours after LipiGesic-M was taken. (In most cases, relief was experienced prior to the 2-hourstudy benchmark.)

LipiGesic-M is highly effective for the treatment of migraine pain and may cost up to 75% less than the leading prescription migraine medications. Available over-the-counter, LipiGesic-M is the best, first-line defense in the treatment of migraine. Each dose of LipiGesic-M is pre-measured; it is easy to use and easy to transport.

# Who should NOT take LipiGesic-M?

LipiGesic-M is extremely safe. It can be used by virtually all migraine sufferers.

# WARNING:

# If pregnant or breast- feeding, ask a health care professional before use.

Also, you should talk to you doctor before using if you have: the worst headache of your life; fever and stiff neck; daily headaches; a headache that is different from your usual migraine; headache that begins after or is caused by head injury, exertion, coughing or bending; experience your first headaches after the age of 50; any continuing medical conditions; migraine headache pain that worsens or continues for more than 48 hours; new or unexpected symptoms.

If a significant allergic reaction occurs, stop using the product and seek immediate medical help.

# Please keep this and all drugs out of the reach of children.

# What side effects are possible with LipiGesic-M?

Few side effects have been reported, but may include: body aches, stomach cramps, vomiting, heartburn, nausea and oral numbness.

# What other drugs could interact with LipiGesic-M?

There are no known drug interactions with LipiGesic-M. However, you should speak with your doctor or pharmacist if you are taking other medications.

# DIRECTIONS

# For maximum effectiveness, begin treatment at first sign of headache.

• Open one unit dose dispenser by tearing off the perforated end and dispensing entire contents under

#### the tongue.



**Important**: Hold in place under the tongue for at least 60 seconds; then swallow.

- Repeat after 5 minutes using a second unit dose dispenser, hold the second dose under the tongue for at least 60 seconds before swallowing.
- Additional medication may be taken after 30 minutes, either I or 2 unit dose dispensers, as needed or as directed by doctor.

# **Active Ingredients:**

Feverfew (3X), Ginger (2X)

# **Other Ingredients:**

N.F. Grade Olive Oil, Silicon Dioxide, Peppermint Flavor

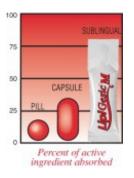
# Indication:

For relief of migraine and associated symptoms.

Use only if dispenser is intact.

# $LipiGesic^{TM}$ -M is fast.

Medications absorbed through the digestive tract generally take up to an hour just to start working, and absorption is highly variable. With the sublingual unit dose system, LipiGesic-M achieves consistent absorption that begins within minutes.



# LipiGesic-M is powerful.

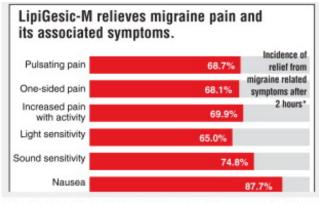
LipiGesic-M's patent-pending formulation, has been shown to be a safe and effective first-line treatment when used at the onset of migraine.\* LipiGesic-M is non-habit forming and not associated with rebound headache.

The active ingredients, Feverfew and Ginger, have had a long history of use and have an excellent safety profile. They have been combined to provide a unique and powerful defense against migraine pain and associated symptoms.

#### **Results at 2 hours post-dose**



After 2 hours, 64% of migraines treated with LipiGesic-M resulted in little or no pain.\*



\* Cady RK, Goldstein J, Nett R, et al. A Double-Blind Placebo-Controlled Pilot study of Sublingual Feverfew and Ginger (LipiGesic<sup>TM</sup>M) in the Treatment of Migraine. Headache. 2011;0017-8748.

#### It's all in the delivery.

LipiGesic<sup>™</sup>-M is a patent - pending medication designed to provide fast and effective relief from the pain and associated symptoms of migraine. Unlike typical pills and capsules, LipiGesic-M starts to work almost immediately



Active ingredients are often destroyed when first passing through the stomach or liver – before they have a chance to reach their intended target. Sublingual (under the tongue) administration prevents this "first pass" destruction by delivering the product directly to the bloodstream through the rich network of blood vessels under the tongue. LipiGesic-M's full- strength active ingredients reach the bloodstream faster and more effectively.



The unit dose system is a patent-pending delivery system developed by PuraMed BioScience, and includes the dispenser as well as specific formula enhancements used to improve the sublingual absorption of LipiGesic-M. The unit dose system is an important part of PuraMed's effort to create products that work faster, are more effective and offer better safety profiles than similar products administered by traditional means.

#### PuraMed™ BIOSCIENCE

Manufactured for **PuraMed BioScience, Inc.** P.O. Box 677, 1326 Schofield Ave. Schofield, WI 54476

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 $\ensuremath{\mathbb{C}}$  PuraMed BioScience 2011 002-1011-1

Principal Display Panel – Box Label

PATENT PENDING HOMEOPATHIC DRUG LipiGesic™ M Fast Relief for Migraine Pain

Net Contents 24 ml (.8115 ounces) Unit Dose Dispeners



LipiGesic M Migraine Headache Pain Reliever



# LIPIGESIC M

feverfew and ginger gel

Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:34331-202		
Route of Administration	SUBLINGUAL				

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
feverfew (UNII: Z64FK7P217) (feverfew - UNII:Z64FK7P217)	feverfew	3 [hp_X] in 1 mL
Ginger (UNII: C5529G5JPQ) (Ginger - UNII:C5529G5JPQ)	Ginger	2 [hp_X] in 1 mL

Inactive Ingredients					
	Ingredient Name		Strength		
Olive Oil (UNII: 6UYK					
Silicon Dioxide (UNII:	ETJ7Z6XBU4)				
Product Characteristics					
Color		Score			
Shape		Size			
Flavor	PEPPERMINT (PEPPERMINT)	Imprint Co	de		
Contains					
Packaging					

#	Item Code	Package Description	Marketing	g Start Date	Ma	rketing End Date	
1	NDC:34331-202-06	8 in 1 BOX					
1		3 mL in 1 DOSE PACK					
Marketing Information							
	Marketing Category	Application Number or Monog	raph Citation	Marketing Start	Date	Marketing End Date	
ur	approved homeopathic			08/08/2011			

# Labeler - PuraMed BioScience, Inc. (627229649)

Establishment					
Name	Address	ID/FEI	Business Operations		
Hillestad Pharmaceutical		029291085	MANUFACTURE		

Establishment					
Name	Address	ID/FEI	Business Operations		
Unette Corporation		0 1140 18 8 2	РАСК		

Revised: 12/2011

PuraMed BioScience, Inc.