# TRAMAPAP - tramadol hydrochloride, acetaminophen Living Well Pharmacy, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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### **Tramapap**

LWP

381 Van Ness Ave. Suite 1507

Torrance CA, 90501

S/N: LWP304326

3/29/2010

LWP,MD

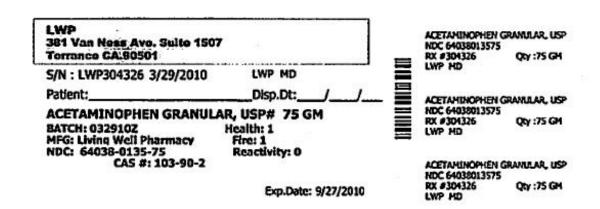
ACETAMINOPHEN GRANULAR, USP #75 GM

BATCH: 03292010Z HEALTH: 1

MFG: LIVING WELL PHARMACY FIRE: 1

NDC: 64038-0135-75 REACTIVITY: 0

CAS #: 103-90-2



**LWP** 

381 Van Ness Ave. Suite 1507

Torrance CA, 90501

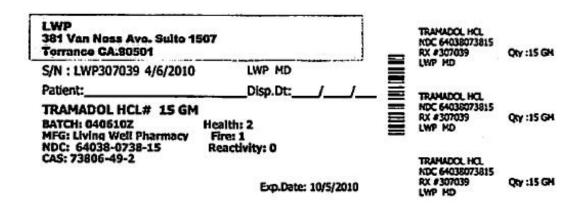
S/N: LWP307039 4/6/2010 LWP,MD

TRAMADOL HCL #15GM

BATCH: 04062010Z HEALTH: 2
MFG: LIVING WELL PHARMACY FIRE: 1

NDC: 64038-0738-15 REACTIVITY: 0

CAS #: 73806-49-2



### 1. RX Only

For Prescription Compounding Only

Tramapap Kit

Tramadol HCl and Acetaminophen Compound Kit

### Description

Each Tramapap Kit is comprised of 15 grams of tramadol hydrochloride powder and 75 grams of acetaminophen powder.

### Certificate of Analysis on File

Tramapap Kit also contains 23.25 grams of Lactose Monohydrate (Spray dried) powder and 1.5 grams of riboflavin USP powder. When compounded, the final product provides a homogeneous product of 300 capsules each capsule containing 50mg of tramadol and 250mg of acetaminophen.

### Equipment

Required supplies needed to compound this kit

### **Equipment**

Item	Quantity
Tramadol HCl (Included)	15 grams
Acetaminophen (Included)	75 grams
Lactose Monohydrate Spray Dried Powder (Included)	23.25 grams
Riboflavin Powder (Included)	1.5 grams
Red/Blue #1 Capsules ( Required Not Included)	300 Capsules

### Equipment

Recommended supplies not included in this kit

Item	Quantity
16 oz Glass Mortar and Pestle	1 each
300 Capsule Machine Number 2 Notch	1
Scraper ( Recommended Not Included)	1
Tamper (Recommended Not Included)	1
Capsule Locker (Recommended Not Included)	1

### Directions

- 1. Using a 16 oz mortar and pestle triturate powders well to reduce particle size until uniform.
- 2. Using a 300 capsule machine encapsulate triturate powder mixture into number 1 red/blue capsules Prior to compounding, store Tramapap Kit at room temperature. Store the final product at room temperature.

Final product for oral use only. Keep out the reach of children. Compounded product, as dispensed, is stable for at least 180 days or the time remaining on the expiration date of any given ingredient, which ever is shorter.

# Tramapap Kit

Tramadol HCl and Acetaminophen Compound Kit

## DESCRIPTION

Each Tramapap Kit is comprised of 15 grams of tramadol hydrochloride powder, USP and 75 grams of acetaminophen.\*

Tramapap kit also contains 23.25 grams of Lactose Monohydrate (Spray dried) powder and 1.5 grams of riboflavin USP powder. When compounded, the final product provides a homogeneous product of 300 capsules each capsule containing 50mg of tramadol and 250mg of acetaminophen.

# **EQUIPMENT**

Required supplies needed to compound this kit

Item	Quantity
Tramadol HCl (included)	15 grams
Acetaminophen (Included)	75 grams
Lactose Monohydrate Spray Dried Powder (Included)	23.25 grams
Riboflavin Powder (Included)	1.5 grams
Red/Blue #1 Capsules (Required; Not included)	300 Capsules

Recommended supplies not included in this kit

Item	Quantity	
16 oz Glass Mortar and Pestle	1 each	
300 Capsule Machine #2 Notch	1	
Scraper (Recommended; Not included)	1	
Tamper (Recommended; Not included)	1	
Capsule Locker (Recommended, Not included)	1	

# DIRECTIONS

- 1. Using a 16 oz mortar and pestle triturate powders well to reduce particle size and until uniform.
- 2. Using a 300 capsule machine encapsulate triturate powder mixture into #1 red/blue capsules

<sup>\*</sup>Certificate of Analysis on file

# Tramapap 50mg/250mg

Tramadol HCl, Acetaminophen Compounding Kit

Active Ingredients: Tramadol HCI 15 grams

Acetaminophen 75 grams

# **RX - For Prescription Compounding Only**

Package Size:

When compounded, the final product provides 300 capsules

Manufactured for:

Living Well Pharmacy, Inc. Torrance, CA 90501

Manufactured by:

Living Well Pharmacy, Inc

### TRAMAPAP

tramadol hydrochloride, acetaminophen kit

### **Product Information**

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:64038-059

Pac	kag	ing

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64038-059-03	1 in 1 KIT		

Quantity of Parts			
Part #	Package Quantity	Total Product Quantity	
Part 1	1 BOTTLE	15 g	
Part 2	1 BOTTLE	75 g	

## Part 1 of 2

## TRAMADOL HCL

tramadol hydrochloride powder

# **Product Information**

Item Code (Source)	NDC:64038-738
Route of Administration	ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Tramadol Hydrochloride (UNII: 9N7R477WCK) (Tramadol - UNII:39J1LGJ30J)	Tramadol Hydrochloride	1 g in 1 g	

Packaging				
#	Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>
1	NDC:64038-738-15	15 g in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/07/2010	

# Part 2 of 2

## **ACETAMINOPHEN CRYSTAL**

acetaminophen powder

Product Information	
Item Code (Source)	NDC:64038-135
Route of Administration	ORAL

# **Active Ingredient/Active Moiety**

	Ingredient Name	Basis of Strength	Strength
l	Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	1 g in 1 g

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:64038-135-75	75 g in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/07/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/07/2010	

# Labeler - Living Well Pharmacy, Inc. (070488957)

# **Registrant** - Living Well Pharmacy, Inc. (070488957)

Establishment				
Name	Address	ID/FEI	Business Operations	
Living Well Pharmacy, Inc.		070488957	api manufacture	

Establishment				
Name	Address	ID/FEI	Business Operations	
Letco		830193582	api manufacture	

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Spectrum Laboratory Products, Inc.		075295246	api manufacture

Establishment				
Name	Address	ID/FEI	Business Operations	
Medisca		627218576	api manufacture	

Revised: 5/2010 Living Well Pharmacy, Inc.