CYCLO/MAG - cyclobenzaprine hydrochloride, magnesium oxide 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.

CYCLO/MAG KIT

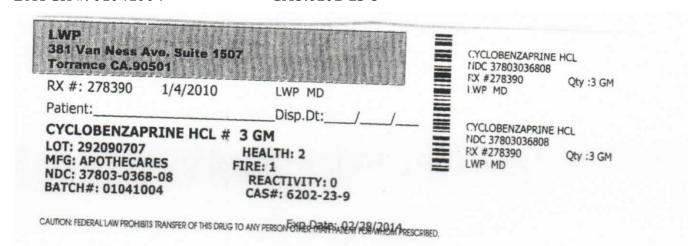
RX #: 278390 1/4/2010 LWP MD

CYLCOBENZAPRINE HCL #3 GM

LOT: 292090707 HEALTH: 2

MFG: APOTHECARES FIRE:1

NDC: 37803-0368-08 REACTIVITY:0 BATCH #: 01041004 CAS:6202-23-9



RX #: 267654 11/10/2009 LWP MD

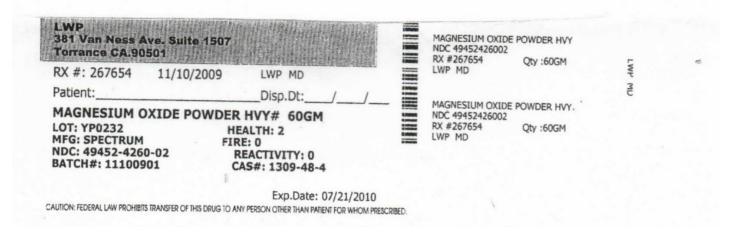
MAGNESIUM OXIDE POWDER HVY #60 GM

LOT: YP0232 HEALTH: 2

MFG: SPECTRUM FIRE:0

NDC: 49452-4260-02 REACTIVITY:0

BATCH #: 11100901 CAS:1309-48-4



1. RX Only

For Prescription Compounding Only

Cyclo/Mag Kit

Cyclobenzaprine HCl and Magnesium Oxide Compound Kit

Description

Each Cyclo/Mag Kit is comprised of 3 grams of cyclobenzaprine hydrochloride powder, USP and 60 grams of magnesium oxide heavy powder.

Certificate of Analysis on File

Cyclo/Mag Kit also contains 60 grams of Lactose Monohydrate (Spray dried) powder and 0.15 grams of riboflavin USP powder. When compounded, the final product provides a homogeneous product of 300 capsules each capsule containing 10mg of cyclobenzaprine and 200mg of magnesium oxide.

Equipment

Required supplies needed to compound this kit

Equipment

Quantity
3 grams
60 grams
60 grams
0.15 grams
300 Capsules

Equipment

Recommended supplies not included in this kit

Equipment

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. Do not use metal bowls or spatulas while

compounding this product.

2. Using a 300 capsule machine encapsulate triturate powder mixture into number 1 red capsules Prior to compounding, store Cyclo/Mag 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.

> RX Only For Prescription Compounding Only

Cyclo/Mag Kit

Cyclobenzaprine HCl and Magnesium Oxide Compound Kit

DESCRIPTION

Each Cyclo/Mag Kit is comprised of 3 grams of cyclobenzaprine hydrochloride powder, USP and 60 grams of magnesium oxide heavy powder.*

Cyclo/Mag kit also contains 60 grams of Lactose Monohydrate (Spray dried) powder and 0.15 grams of riboflavin USP powder. When compounded, the final product provides a homogeneous product of 300 capsules each capsule containing 10 mg of cyclobenzaprine and 200 mg of magnesium oxide.

Required supplies needed to compound this kit

Item	Quantity	
Cyclobenzaprine HCl (included)	3 grams	
Magnesium Oxide Heavy Powder (Included)	60 grams	
Lactose Monohydrate Spray Dried Powder (Included)	60 grams	
Riboflavin Powder (Included)	0.15 grams	
Red #1 Capsules (Required; Not included)	300 Capsules	

Recommended symplies 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

Using a 16 oz mortar and pestle triturate powders well to reduce particle size and until uniform. Do not use metal bowls or spatulas while compounding this product.
Using a 300 capsule machine encapsulate triturate powder mixture into #1 red capsules.

Prior to compounding, store CycloMag Kit at room temperature. Store the final product at room

Final product for oral use only. Keep out of the reach of children. Compounded product, as dispensed, is stable for at least 130 days or the time remaining on the expiration date of any given ingredient, which ever is shorter.

*Certificate of Analysis on file

CYCLO/MAG

cyclobenzaprine hydrochloride, magnesium oxide kit

Product Information

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:64038-313

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:64038-313-04	1 in 1 KIT		

Quantity of Parts

Quantity of Lucio		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	3 g
Part 2	1 BOTTLE	60 g

Part 1 of 2

CYCLOBENZAPRINE HCL

cyclobenzaprine hydrochloride powder

Product Information

Item Code (Source)	NDC:64038-325
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYCLOBENZAPRINE HYDRO CHLORIDE (UNII: 0 VE05JYS2P) (CYCLOBENZAPRINE - UNII:69O5WQQ5TI)	CYCLOBENZAPRINE HYDROCHLORIDE	1 g in 1 g

Packaging

# Item	Code Package Descripti	ion Marketing Start Date	Marketing End Date
1 NDC:64038-3	325-03 3 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/03/2010	

Part 2 of 2

MAGNESIUM OXIDE

magnesium oxide powder

Product Information

Item Code (Source) NDC:64038-131

Route of Administration ORAL

Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength
IIM OXIDE (IINII: 3A3	LIOCITIC) (MAGNESILIM OXIDE - LINII:3A3LIOCITIC)	MAGNESIUMOXIDE	1 σ in 1 σ

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64038-131-60	60 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/03/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/03/2010	

Labeler - Living Well Pharmacy, Inc. (070488957)

Registrant - Living Well Pharmacy, Inc. (070488957)

Establishment

Name	Address	ID/FEI	Business Operations
Living Well Pharmacy, Inc.		070488957	repack

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Supply		859501871	api manufacture

Ls	tal	D.	lIS	h	m	e	n	t

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	Name	Address	ID/FEI	Business Operations		
Spec	ctrum Laboratory Products, Inc.		075295246	api manufacture		

Revised: 3/2010 Living Well Pharmacy, Inc.