CYCLOPHENE- cyclophene
California Pharmaceuticals LLC

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.

CYCLOPHENE - 70332-102

Instructions for Pharmacist
Page 1
Page 2

NDC 70332-102-01

For Prescription Compounding Only

Rx only

RapidPaq™
CYCLOPHENE™
(5% cyclobenzaprine hydrochloride topical cream kit)

RapidPaq™ kits provide a convenient approach to rapidly prepare prescription medications, as all components are pre-measured. This kit is manufactured according to US FDA current Good Manufacturing Practices (cGMP).

Description:
This kit contains active and inactive materials to prepare approximately 111.2 grams of Cyclobenzaprine Hydrochloride topical cream. **This kit may only be used for prescription compounding by an appropriate licensed medical professional, in response to a physician's prescription, to create a medication tailored to the specialized needs of an individual patient.**

Active Ingredients:
- 5.6 g Cyclobenzaprine Hydrochloride [equivalent to 4.9 g Cyclobenzaprine]

Inactive Ingredients:
- 100 g RapidPaq Cream Base (D. l Water, Cetearyl Alcohol, Cyclomethicone, Polysorbate-60, Sorbitol, Phenoxyethanol(and)ethylhexylglycerin,
Tocopheryl Acetate, Aloe Barbadensis, Disodium EDTA)
- 5.6 Ethoxy Diglycol
- Spatula
- Instructions

Pharmacist Instructions for Preparation

1 Remove and Inspect the Contents of the Kit

Ensure that all components are present. Ensure that the safety seals are present on the Cyclobenzaprine Hydrochloride, ethoxy diglycol and RapidPaq Cream Base. If components are missing or the safety seals are not intact do not use the kit.

2 Prepare for Mixing

Wear gloves and eye protection during mixing operations. Remove the cap and seal from the RapidPaq Cream Base. Break the perforated seal and remove the cap from the Cyclobenzaprine Hydrochloride and ethoxy diglycol.

3 Dissolve the Cyclobenzaprine Hydrochloride

Using a spatula make a well in the center of the RapidPaq Cream Base. Transfer approximately half of the ethoxy diglycol to the Cyclobenzaprine Hydrochloride bottle. Cap the Cyclobenzaprine Hydrochloride bottle and shake to ensure that all residue Cyclobenzaprine Hydrochloride has been dissolved. Pour the contents into the RapidPaq Cream Base. Repeat this step with the remaining ethoxy diglycol.

4 Complete the Mixing Process

Using the spatula, mix the RapidPaq Base jar that now contains the ethoxy diglycol and cyclobenazprine hydrochloride ingredients thoroughly for about 2 minutes or until fully dissolved.

5 Relabel the Resulting Cream

Label the resulting topical cream as required for prescription products. Ensure that the original RapidPaq Cream Base label is removed or obscured, since the original label is no longer accurate once the cream is prepared.

Discard the spatula.

Store the unused kit at room temperature of 15-30°C (59-86°F). Once prepared, store the topical cream between 15-30°C (59-86°F). The final cream is stable for up to eight weeks.

U.S. Patents Pending

Repackaged and Distributed by:
California Pharmaceuticals, LLC
768 Calle Plano
Camarillo, CA 93012

California
PHARMACEUTICALS LLC

CS107-A1 rev 3

NDC 70332-102-01 For Prescription Compounding Only **Rx only**

RapidPaq™ CYCLOPHENE™

(5% cyclobenzaprine hydrochloride topical cream kit)

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Active Ingredients:
- 5.6 g Cyclobenzaprine Hydrochloride [equivalent to 4.9 g Cyclobenzaprine]

Inactive Ingredients:
- 100 g RapidPaq Cream Base (D.I Water, Cetearyl Alcohol , Cyclomethicone, Polysorbate-60, Sorbitol, Phenoxyethanol(and) ethylhexylglycerin, Tocopheryl Acetate, Aloe Barbadensis, Disodium EDTA)
- 5.6g Ethoxy Diglycol
- Spatula
- Instructions

Pharmacist
Instructions for Preparation

1 Remove and Inspect the Contents of the Kit

Ensure that all components are present. Ensure that the safety seals are present on the Cyclobenzaprine Hydrochloride, ethoxy diglycol and RapidPaq Cream Base. If components are missing or the safety seals are not intact do not use the kit.

2 Prepare for Mixing

Wear gloves and eye protection during mixing operations. Remove the cap and seal from the RapidPaq Cream Base. Break the perforated seal and remove the cap from the Cyclobenzaprine Hydrochloride and ethoxy diglycol.

NDC 70332-102-01 For Prescription Compounding Only **Rx only**

RapidPaq™ CYCLOPHENE™

(5% cyclobenzaprine hydrochloride topical cream kit)

Pharmacist
Instructions for Preparation (continued)

3 Dissolve the Cyclobenzaprine Hydrochloride

Using the spatula make a well in the center of the RapidPaq Cream Base

Using the spatula make a well in the center of the RapidPaq Cream Base. Transfer the Cyclobenzaprine Hydrochloride to the well of the RapidPaq Cream Base. Transfer approximately half of the ethoxy diglycol to the Cyclobenzaprine Hydrochloride bottle. Cap the Cyclobenzaprine Hydrochloride bottle and shake to ensure that all residual Cyclobenzaprine Hydrochloride has been dissolved. Pour the contents into the RapidPaq Cream Base. Repeat this step with the remaining ethoxy diglycol.

4 Complete the Mixing Process

Using the spatula, mix the RapidPaq Base jar that now contains the ethoxy diglycol and cyclobenazprine hydrochloride ingredients thoroughly for about of 2 minutes or until fully dissolved.

5 Relabel the Resulting Cream

Label the resulting topical cream as required for prescription products. Ensure that the original RapidPaq Cream Base label is removed or obscured, since the original label is no longer accurate once the cream is prepared.

Discard the spatula.

Store the unused kit at room temperature of 15-30°C (59-86°F). Once prepared, store the topical cream between 15-30°C (59-86°F).The final cream is stable for up to eight weeks.

U.S. Patents Pending

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California Pharmaceuticals, LLC
768 Calle Plano
Camarillo, CA 93012

CS107-A1 rev 3

Cyclobenzaprine Hydrochloride product label

Do not use if saety seal is broken

Cyclobenzaprine Hydrochloride

1-propanamine, 3-(5H-dibenzo[a,d]cycloheptenn-5-ylidene)-N,N-dimethyl-, hydrochloride

RxOnly

CAS # 6202-23-9

Net contents 5.6 g

Repackaged by:

California Pharmaceuticals, LLC

Camarillo, CA 93012

California

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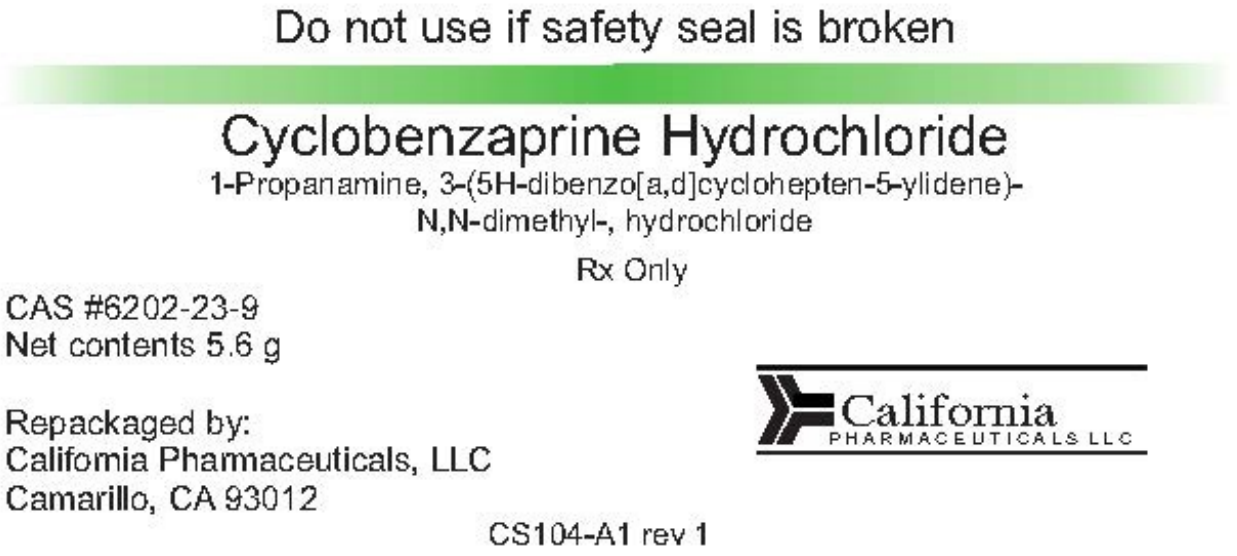
CS104-A1 rev 1



RapidPaq Cream Base product label

Do not use if seal is broken

RapidPaq™ Cream base

Net contents: 100 g

Ingredients: (D.l Water, Cetearyl Alcohol, Cyclomethicone, Polysorbate-60, Sorbitol, Phenoxyethanol(and)ethylhexylglycerin, Tocopheryl Acetate,

Aloe barbadensis, Disodium EDTA.)

RX Only

Manufactured for California Pharmaceyticals, LLC, Camarillo, CA 93012

Do not use if seal is broken

California PHARMACEUTICALS LLC

RapidPaq™ Cream Base

Net contents: 100 g

Ingredients: (D.I Water, Cetearyl Alcohol , Cyclomethicone, Polysorbate-60, Sorbitol, Phenoxyethanol(and) ethylhexylglycerin, Tocopheryl Acetate, Aloe Barbadensis, Disodium EDTA,)

Rx Only
Manufactured For California Pharmaceuticals, LLC, Camarillo, CA 93012

CYCLOPHENE Kit product label

NDC 70332-102-01

Rx only

RapidPaq™

Kit for Topical Cream

CYCLOPHENE™

(5% cyclobenzaprine hydrochloride topical cream kit)

Muscle relaxant

Store at room temperature,

15-30°C (59-86°F)

Description:

This kit contains active and inactive materials to prepare approximately 111.2 grams of Cyclobenzaprine Hydrochloride topical cream. **This kit may only be used for prescription compounding by an appropriate licensed medical professional, in response to a physician's prescription, to create a medication tailored to the specialized needs of an individual patient.**

Active ingredient

- 5.6 g Cyclobenzaprine Hydrochloride USP [equivalent to 4.9 g Cyclobenzaprine]

Inactive Ingredients:

- 100 g RapidPaq Cream Base(D.l Water, Cetearyl Alcohol, Cyclomethicone, Polysorbate-60, Sorbitol, Phenoxyethanol(and) ethylhexylglycerin,

Tocopheryl Acetate, Aloe Barbadensis, Disodium EDTA)

- 5.6 g Ethoxy Diglycol
- Spatula
- Instructions

U.S. Patents Pending

Do not use if safety seal is broken

California

PHARMACEUTICALS LLC

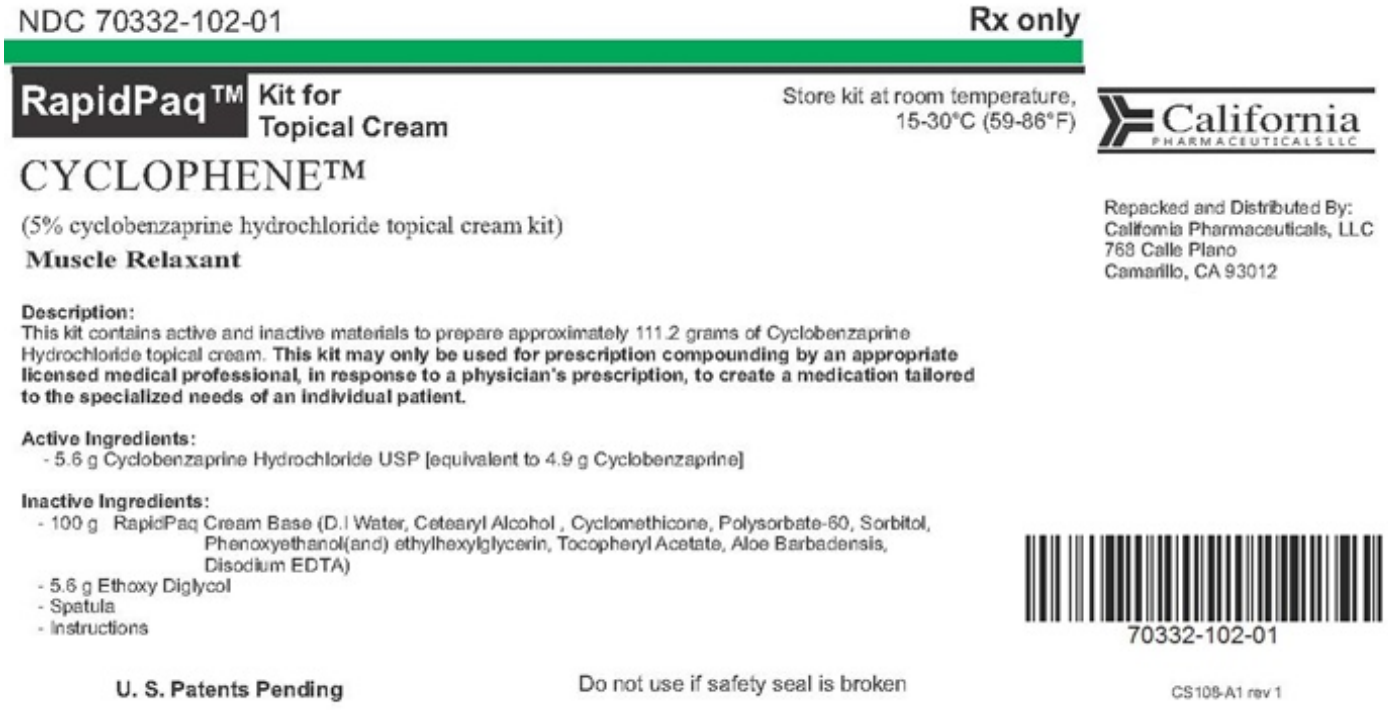
Repacked and Distributed By;

Caifornis Pharmaceuticals, LLC

768 Calle Plano

Camarillo, CA 93012

CS 108-A1 rev 1



CYCLOPHENE

cyclophene kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70332-102

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70332-102-01	1 in 1 KIT	01/01/2016	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	5.6 g
Part 2	1 BOTTLE	5.6 g
Part 3	1 JAR	100 g

Part 1 of 3

ETHOXY DIGLYCOL

diethylene glycol monoethyl ether liquid

Product Information	
Route of Administration	TOPICAL

Inactive Ingredients	
Ingredient Name	**Strength**
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		5.6 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
unapproved drug other		01/01/2016	

Part 2 of 3

CYCLOBENZAPRINE HYDROCHLORIDE

cyclobenzaprine hydrochloride powder

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CYCLOBENZAPRINE HYDROCHLORIDE (UNII: 0VE05JYS2P) (CYCLOBENZAPRINE - UNII:69O5WQQ5TI)	CYCLOBENZAPRINE HYDROCHLORIDE	5.6 g in 5.6 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		5.6 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2016	

Part 3 of 3

RAPIDPAQ CREAM BASE

rapidpaq cream base cream

Product Information

Route of Administration	TOPICAL

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SORBITOL (UNII: 506T60A25R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		100 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2016	

Labeler - California Pharmaceuticals LLC (021420944)

Registrant - California Pharmaceuticals LLC (021420944)

Establishment

Name	Address	ID/FEI	Business Operations
California Pharmaceuticals LLC		021420944	manufacture(70332-102) , repack(70332-102)

Revised: 7/2016 California Pharmaceuticals LLC