**TABRADOL- cyclobenzaprine hydrochloride**
**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.*

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**Tabradol**

**Tabradol - Pharmacist Instructions page 2**

NDC 70332-106-01 For Prescription Compounding Only **Rx only**

**RapidPaq™** TABRADOL™

Cyclobenzaprine hydrochloride 1.13 mg/mL [equivalent to 1 mg/mL cyclobenzaprine ]
Cherry oral suspension kit

## Pharmacist Preparation Instructions (continued)

### 3 Transfer the Oral Suspension Vehicle to the Cyclobenzaprine Hydrochloride Bottle

Uncap the oral suspension bottle. Pour a small amount of the oral suspension liquid (approximately one-third to one-half the volume of the cyclobenzaprine hydrochloride bottle) into the cyclobenzaprine hydrochloride bottle. Cap the cyclobenzaprine bottle and shake well several times to dissolve the cyclobenzaprine hydrochloride powder. Empty the dissolved contents back into the oral suspension bottle. Cap and shake well the oral suspension bottle. Repeat this step a minimum of 3 times. Visually ensure that all of the cyclobenzaprine hydrochloride has been dissolved and transferred to the suspension bottle.

### 4 Transfer the Oral Suspension Vehicle that now contains the suspended Cyclobenzaprine Hydrochloride to the Cherry Flavoring Bottle

Uncap the oral suspension bottle that now contains the suspended cyclobenzaprine hydrochloride. Uncap the bottle that contains the cherry flavoring. Pour the entire contents of the oral suspension bottle into the cherry flavoring bottle. Shake vigorously by inverting the bottle repeatedly several times.

### 5 Complete the Combining Process

Press the oral syringe adaptor into the cherry flavor bottle suspension. Recap the flavor bottle, which now contains the cyclobenzaprine hydrochloride, suspension. Shake well by inverting repeatedly several times.

### 6 Re-label the Resulting Final Suspension

Label the resulting final suspension as required for prescription products. Ensure that the original cherry

oral suspension vehicle label is removed or obscure since the since the original label is no longer accurate once the resulting final suspension is completed. The contents of the bottle need to be shaken well before taken as directed by the medical professional.

*Store the unused kit at room temperature of 15-30°C (59-86°F). Once prepared, store the mixed suspension between 15-30°C (59-86°F). The resulting final suspension is stable for up to eight weeks based upon real-time and accelerated stability studies.*

*An oral syringe is provided in the kit and may be used to facilitate accurate delivery of the suspension.*

**U.S. Patents Pending**

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

CS34-A1 rev 4

**Tabradol - Label**

Do not use if safety seal is broken

# Cyclobenzaprine Hydrochloride

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

Rx Only

CAS #6202-23-9
Net contents 0.28 g

Repackaged by:
Califomia Pharmaceuticals, LLC
Camarillo, CA 93012

CS22-A1 rev 5

**Tabradol - Inactive ingredient - flavor label**

Do not use if safety seal is broken

# TABRADOL Cherry
# Oral Suspension Vehicle

Sugar, dye, and paraben free

**Contents:** purified water, glycerin, sorbitol, cherry flavor, potassium sorbate, xanthan gum, sodium saccharin sodium benzoate, sodium citrate, citric acid.

California PHARMACEUTICALS LLC

Net Contents:
250 ml (8.5 fl oz)

Manufactured for:
California Pharmaceuticals LLC
Camarillo, CA 93012

CS26-A1 rev 3

**Tabradol - Pharmacist instructions Page 1**

NDC 70332-106-01 For Prescription Compounding Only

RapidPaq™ TABRADOL™

Cyclobenzaprine hydrochloride 1.13 mg/mL [equivalent to 1 mg/ml
Cherry oral suspension - kit

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

Description:
This kit contains active and inactive materials to prepare 250 ml of a

suspension containing 1.15 mg/mL cyclobenzaprine hydrochloride [equivalent to 1 mg/mL cyclobenzaprine].

Contents:
- 0.28 g cyclobenzaprine hydrochloride USP [equivalent to 0.25 g c
- 125 mL Cherry flavor vehicle (purified water, glycerin, cherry flavo potassium sorbate, xanthan gum, sodium saccharin, sodium bena citrate, citric acid)
- 125 ml oral suspension vehicle (purified water, potassium sorbate citric acid)
- Bottle adaptor for oral syringe
- Oral syringe
- Instructions

## Pharmacist Instructions for Preparation

### 1 Remove and Inspect the Contents of the Kit

Ensure that the safety seals are present and intact on the cyclobenza glass vial, the Cherry flavoring bottle and the oral suspension bottle. intact, do not use the kit.

### 2 Prepare for Compounding

Wear gloves and eye protection during compounding operations. Rer from the Cherry flavor bottle and the oral suspension bottle. Break the remove the cap from the cyclobenzaprine hydrochloride bottle.

CS34-A1 rev 4

**Tabradol - Principal Label**

NDC 70332-106-01 Rx only

RapidPaq™ Cherry Oral Suspension Kit

Store kit at room temperature, 15-30°C (59-86°F)

California PHARMACEUTICALS LLC

Repacked and Distributed By:
California Pharmaceuticals, LLC
768 Calle Plano
Camarillo, CA 93012

# TABRADOL™

(cyclobenzaprine hydrochloride 1.13mg/mL [equivalent to 1 mg/mL cyclobenazaprine], In a Cherry oral suspension- kit) **Muscle Relaxant**

**Description:**
This kit contains active and inactive materials to prepare approximately 250mL of a cherry oral suspension containing 1.13 mg/mL of cyclobenzaprine hydrochloride [equivalent to 1 mg/mL of cyclobenzaprine]. **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:**
- 0.28g cyclobenzaprine hydrochloride USP [equivalent to 0.25g cyclobenzaprine]

**Inactive Ingredients:**
- Bottle containing 125 mL flavor vehicle (purified water, glycerin, cherry flavor, sorbitol, potassium sorbate, xathan gum, sodium saccharin, sodium benzoate, sodium citrate, citric acid)
- Bottle containing 125 ml oral suspension vehicle (purified water, potassium sorbate, sodium benzoate, citric acid)
- Press-in bottle adaptor for oral dispenser
- Oral Dispenser
- Instructions

70332-106-01

**U. S. Patents Pending**

Do not use if safety seal is broken

CS125-A1 rev 2

## TABRADOL
cyclobenzaprine hydrochloride kit

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70332-106 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:70332-106-01 | 1 in 1 KIT | | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | 1 BOTTLE, PLASTIC | 125 mL |
| **Part 2** | 1 BOTTLE, GLASS | 0.25 g |
| **Part 3** | 1 BOTTLE, PLASTIC | 125 mL |

## Part 1 of 3

## STRUCTURED SUSPENSION VEHICLE
suspension liquid

| Product Information | |
|---|---|
| **Route of Administration** | ORAL |

| Inactive Ingredients | |
|---|---|
| Ingredient Name | Strength |
| **SORBITOL** (UNII: 506T60A25R) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **POTASSIUM SORBATE** (UNII: 1VPU26JZZ4) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **DIMETHYL SULFONE** (UNII: 9H4PO4Z4FT) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |

| Packaging | | | | |
|---|---|---|---|---|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| **1** | | 125 mL in 1 BOTTLE, PLASTIC; 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, for suspension

| Product Information | |
|---|---|
| **Route of Administration** | ORAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| Ingredient Name | Basis of Strength | Strength |
| **CYCLOBENZAPRINE HYDROCHLORIDE** (UNII: 0VE05JYS2P) (CYCLOBENZAPRINE - UNII:69O5WQQ5TI) | CYCLOBENZAPRINE HYDROCHLORIDE | 0.25 g in 0.25 g |

| Packaging | | | | |
|---|---|---|---|---|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| **1** | | 0.5 g in 1 BOTTLE, GLASS; 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

## STRUCTURED FLAVORING VEHICLE

flavor liquid

### Product Information

| | |
|---|---|
| **Route of Administration** | ORAL |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **CHERRY** (UNII: BUC5I9595W) | |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **POTASSIUM SORBATE** (UNII: 1VPU26JZZ4) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 125 mL in 1 BOTTLE, PLASTIC; 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)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| California Pharmaceuticals, LLC | | 021420944 | manufacture(70332-106) , repack(70332-106) |

Revised: 1/2016 California Pharmaceuticals, LLC