SYNAPRYN- tramadol 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.

Synapryn 107

Pharmacist Instructions For Preparation

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1 Remove and Inspect the Contents of the Kit

Ensure that the safety seals are present and intact on the tramadol hydrochloride glass vial, the cherry flavoring bottle, and the oral suspension bottle. If the seals are not intact, do not use the kit.

2 Prepare for Combining

Wear gloves and eye protection during the compounding operations. Remove the seals from the Cherry flavor bottle and the oral suspension bottle. Break the perforated seal and remove the cap from the tramadol hydrochloride bottle.

3 Transfer the Oral Suspension Vehicle to the Tramadol 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 tramadol hydrochloride bottle) into the tramadol hydrochloride bottle. Cap the tramadol bottle and shake well several times to dissolve the tramadol 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 tramadol hydrochloride has been dissolved and transfered to the suspension bottle.

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

Uncap the oral suspension bottle that now contains the suspended tramadol 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 suspension, which now contains the tramadol hydrochloride. 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 obscured 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.

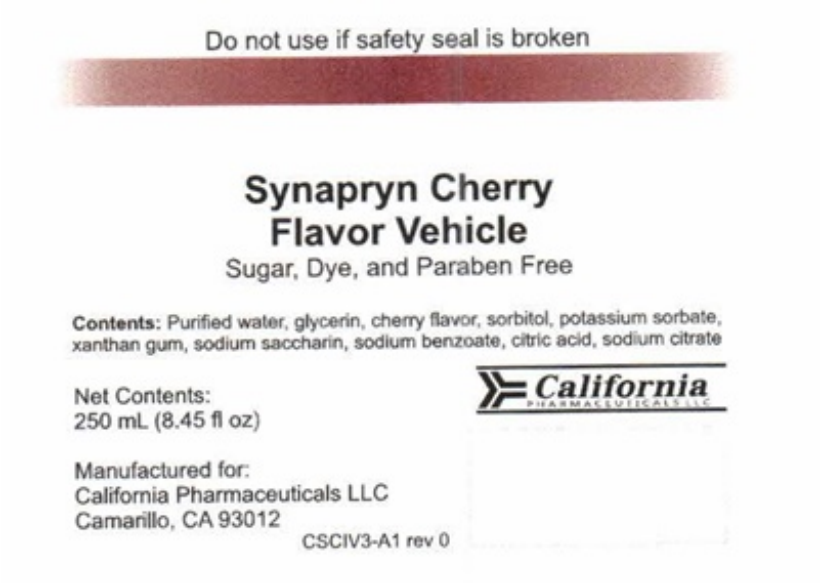
Store the unused kit at room temperature of 15-30°C (59-86°F). Once prepared, store the resulting final suspension between 15-30°C (59-86°F). The resulting final suspension is stable for up to eight weeks based upon the real-time and accelerated stability studies.

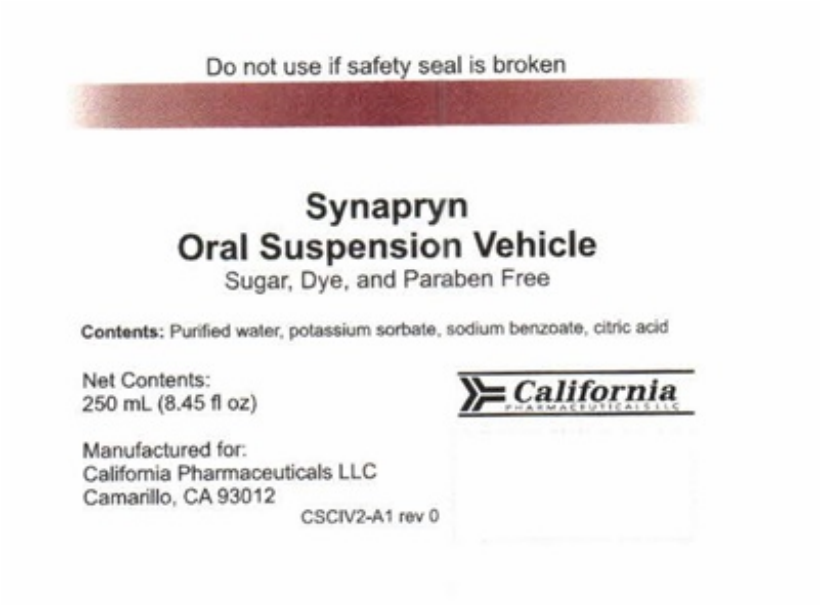
An oral dispenser is provided in the kit and may be used to facilitate the accurate delivery of the suspension.

U.S. Patents Pending

Manufactured and repacked by:
California Pharmaceuticals, LLC
768 Calle Plano
Camarillo, CA 93012

CSCIV7 rev 0





NDC 70332-107-01 For Prescription Compounding Only **Rx only**

RapidPaq™ SYNAPRYN™ CIV

(tramadol hydrochloride 11.4 mg/mL [equivalent to 10.0 mg/mL tramadol] Cherry oral suspension- kit)

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

Description:
This kit contains active and inactive materials to prepare 500 mL of a tramadol hydrochloride cherry oral suspension containing 11.4 mg/mL tramadol hydrochloride [equivalent to 10.0 mg/mL tramadol]. **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.**

Contents:
- 5.8 g tramadol hydrochloride USP [equivalent to 5.1 g tramadol]
- 250 mL Cherry Flavor Vehicle (purified water, glycerin, cherry flavor, sorbitol, potassium sorbate, xanthan gum, sodium saccharin, sodium benzoate, sodium citrate, citric acid)
- 250 mL Oral Suspension vehicle (purified water, potassium sorbate, sodium benzoate, citric acid)
- Press in bottle adaptor
- Oral dispenser
- Instructions

Pharmacist Instructions for Preparation

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RapidPaq™ SYNAPRYN™ CIV

(tramadol hydrochloride 11.4 mg/mL[equivalent to 10.0 mg/mL tramadol]
Cherry oral suspension- kit)

Pharmacist
Instructions for Preparation (continued)

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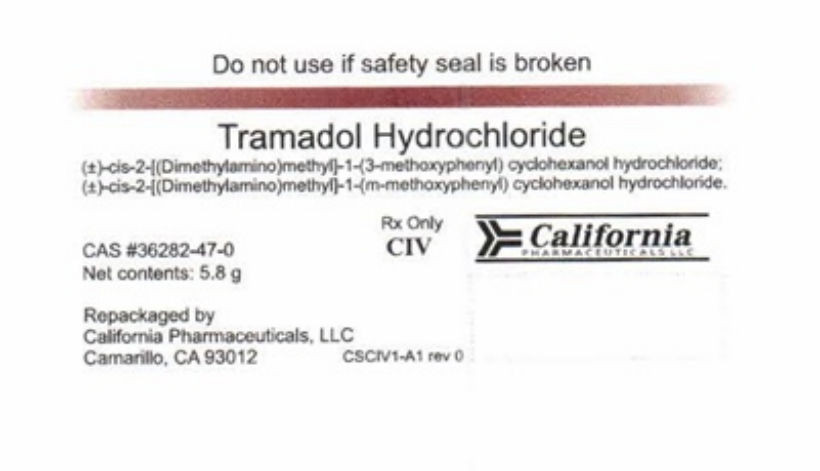
CSCIV7 rev 0

Label



Synapryn - 107 product label

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Contains:

- 5.8 g tramadol hydrochloride USP [equivalent to 5.1 g tramadol]

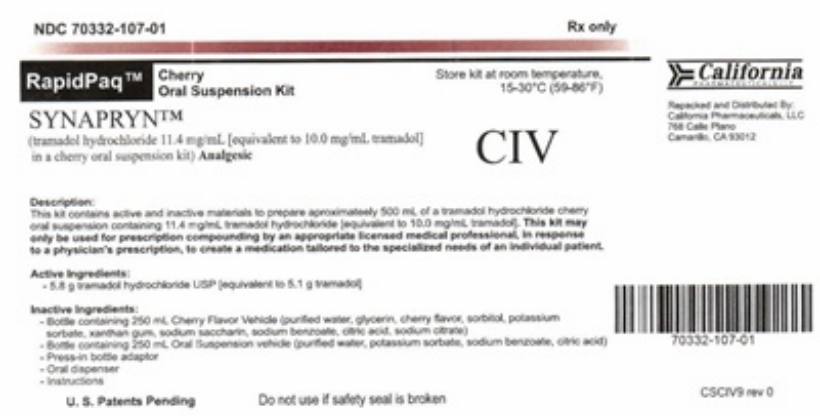
- 250 mL Cherry Flavor Vehicle (purified water, glycerin, cherry flavor, sorbitol, potassium sorbate, xanthan gum, sodium saccharin, sodium benzoate, sodium citric acid)

- 250 mL Oral Suspension vehicle (purified water, potassium sorbate, sodium benzoate, citric acid)

- Press in bottle adaptor

- Oral dispenser

- Insructions



SYNAPRYN

tramadol hydrochloride kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70332-107

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70332-107-01	1 in 1 KIT	05/01/2017	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 VIAL, GLASS	5.8 g
Part 2	1 BOTTLE	250 mL
Part 3	1 BOTTLE	250 mL

Part 1 of 3

TRAMADOL HYDROCHLORIDE

tramadol hydrochloride powder, for solution

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRAMADOL HYDROCHLORIDE (UNII: 9N7R477WCK) (TRAMADOL - UNII:39J1LGJ30J)	TRAMADOL HYDROCHLORIDE	5.8 g in 5.8 g

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5.8 g in 1 VIAL, 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		05/01/2017	

Part 2 of 3

SYNAPRYN VEHICLE

synapryn vehicle liquid

Product Information	
Route of Administration	ORAL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		250 mL 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		05/01/2017	

Part 3 of 3

FLAVOR VEHICLE

flavor vehicle liquid

Product Information	

Route of Administration	ORAL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		250 mL 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		05/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2017	

Labeler - California Pharmaceuticals, LLC (021420944)

Registrant - California Pharmaceuticals, LLC (021420944)

Establishment

Name	Address	ID/FEI	Business Operations
California Pharmaceuticals, LLC		021420944	manufacture(70332-107) , relabel(70332-107) , repack(70332-107)