DICOPANOL- diphenhydramine 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.

Dicopanol

Dicopanol, Instructions for Use, Page 2

NDC 70332-109-01 For Prescription Compounding Only

RediPak DICOPANOL™

(diphenhydramine hydrochloride 5.7 mg/mL [equivalent to 5.0 mg/mL diphenh
Pineapple/Orange oral suspension - kit

Pharmacist
Preparation Instructions (continued)

3 Transfer Diphenhydramine Hydrochloride to the Pinea
Suspension Bottle

Uncap the Pineapple/Orange suspension bottle. Pour a small amount c
suspension liquid (approximately one-third to one-half the volume of th
hydrochloride bottle) into the diphenhydramine hydrochloride bottle. Ca
hydrochloride bottle and shake well several times to dissolve the diphe
hydrochloride powder. Empty the contents into the Pineapple/Orange s
Cap and mix the suspension bottle. Repeat this step minimum of 3 time
all of the diphenhydramine hydrochloride has been dissolved and trans
bottle.

4 Complete the Compounding Process

Insert the press-in bottle adaptor into the Pineapple/Orange suspensi
contains the suspended diphenhydramine hydrochloride . Recap the
suspension bottle. Shake well by inverting repeatedly several times.

5 Re-label the Resulting Final Suspension

Label the resulting final suspension as required for prescription produ
original Pineapple/Orange oral suspension vehicle label is removed c
original label is no longer accurate once the resulting final suspensio
contents of the bottle need to be shaken well before taken as directec
professional.

Store the unused kit at room temperature of 15-30°C (59-86°F). Once

store the resulting final suspension between 15-30° C (59-86° F). The suspension is stable for up to eight weeks, based upon real-time and stability studies.

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

U.S. Patents Pending

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

CS67-A1 rev 3

Instructions for Preparation - page 1

NDC 70332-103-01 For Prescription Compounding Only **Rx only**

RapidPaq™ DICOPANOL™

(diphenhydramine hydrochloride 5.7 mg/mL [equivalent to 5.0 mg/mL diphenhydramine mg/mL]
Pineapple/Orange oral suspension - 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 Practice (cGMP).

Description:
This kit contains active and inactive materials to prepare a diphenhydramine hydochloride Pineapple/Orange oral suspension.These instructions describe how to prepare 150 mL of Pineapple/Orange oral suspension containing 5.7 mg/mL diphenhydramine hydrochloride [equivalent to 5.0 mg/mL diphenhydramine]. **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:
- 0.86 g diphenhydramine hydrochloride USP [equivalent to 0.75g diphenhydrmaine]
- 150 mL Pineapple/Orange oral suspension vehicle (purified water, glycerin, xylitol, monoammonium glycyrrhizinate, pineapple flavor, orange flavor, potassium sorbate, xanthan gum, sodium benzoate, citric acid, sodium citrate)
- Press-in bottle adapter

- Press-in bottle adaptor
- Oral dispenser
- 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 diphenhydramine hydrochloride and the Pineapple/Orange oral suspension vehicle bottles. If the seals are not intact, do not use the kit.

2 Prepare for Compounding

Wear gloves and eye protection during combining operations. Remove the seal from the Pineapple/Orange oral suspension bottle. Break the perforated seal and remove the cap from the diphenhydramine hydrochloride bottle.

Diphenhydramine - label

Dicopanol. Package Label

NDC 70332-103-01

Rx only

RapidPaq™ **Pineapple/Orange Oral Suspension Kit**

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

California PHARMACEUTICALS LLC

DICOPANOL™

(diphenhydramine hydrochloride 5.7 mg/mL [equivalent to 5.0 mg/mL diphenhydramine], In a Pineapple/Orange oral suspension kit) **Antihistamine**

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

Description:
This kit contains active and inactive materials to prepare approximately 150mL of a diphenhydramine hydrochloride pineapple/orange oral suspension containing 5.7 mg/mL of diphenhydramine hydrochloride [equivalent to 5.0 mg/mL diphenhydramine]. **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:
- 0.86g diphenhydramine hydrochloride, USP [equivalent to 0.75g diphenhydramine]

Inactive Ingredients:
- 150mL oral suspension vehicle (purified water, glycerin, xylitol, monoammonium glycyrrhizinate, pineapple flavor, orange flavor,potassium sorbate, xanthan gum, sodium benzoate, citric acid, sodium citrate)
- Press-in bottle adaptor
- Oral Dispenser
- Instructions

70332-103-01

U. S. Patents Pending

Do not use if safety seal is broken

CS119-A1 rev 2

Dicopanol - Flavor Suspension label

DICOPANOL

diphenhydramine hydrochloride kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70332-103

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70332-103-01	1 in 1 KIT		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, GLASS	0.86 g
Part 2	1 BOTTLE, PLASTIC	150 mL

Part 1 of 2

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride powder, for suspension

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	0.86 g in 0.86 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		0.75 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 2 of 2

ORAL SUSPENSION VEHICLE

suspension liquid

Product Information

Route of Administration	ORAL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCYRRHIZIN, AMMONIATED (UNII: 3VRD35U26C)	
PINEAPPLE (UNII: 2A88ZO081O)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ORANGE (UNII: 5EVU04N5QU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MELATONIN (UNII: JL5DK93RCL)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
STEVIA LEAF (UNII: 6TC6NN0876)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		150 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)

Registrant - California Pharmaceuticals LLC (021420944)

Establishment

Name	Address	ID/FEI	Business Operations
California Pharmaceuticals LLC		021420944	manufacture(70332-103)