DICOPANOL- diphenhydramine hydrochloride
Fusion 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

Principal Display Panel

Do not use if safety seal is broken

NDC 43093-104-01

Rx only

FusePaq™ Oral Suspension Kit

DICOPANOL™

(diphenhydramine hydrochloride 5 mg/mL, in oral suspension kit)

Description:
This kit contains active and inactive bulk materials to prepare 150 mL of a diphenhydramine hydrochloride oral suspension containing 5 mg/mL diphenhydramine hydrochloride. This kit may only be used for the extemporaneous combining of these ingredients 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:

- 0.75 g diphenhydramine hydrochloride, USP

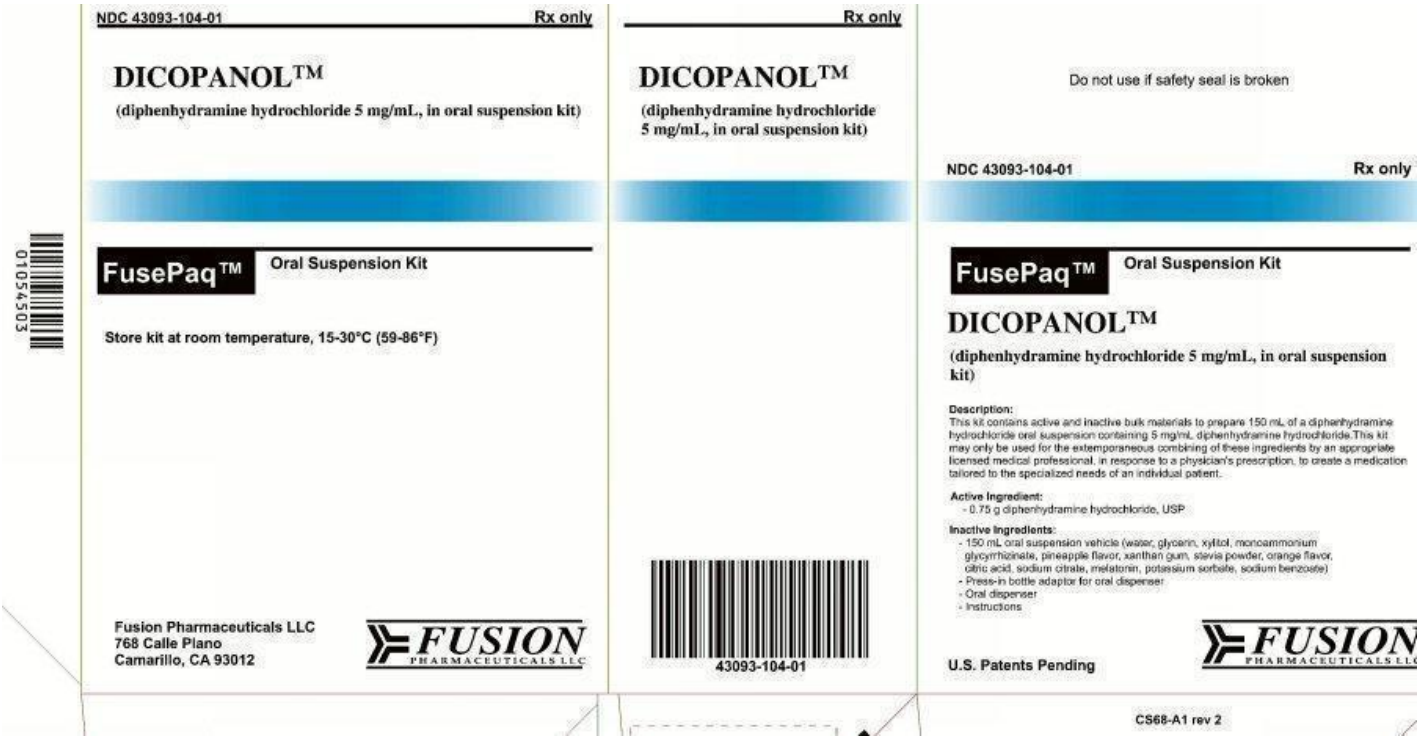
Inactive Ingredients:

- 150 mL oral suspension vehicle (water, glycerin, xylitol, monoammonium glycyrrhizinate, pineapple flavor, xanthan gum, stevia powder, orange flavor, citric acid, sodium citrate, melatonin, potassium sorbate, sodium benzoate)
- Press-in bottle adaptor for oral dispenser
- Oral dispenser
- Instructions

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

U.S. Patents Pending FUSION PHARMACEUTICALS 786 Calle Plano Camarillo CA 93012

CS68-A1 rev 2



Drug Label

Do not use if safety seal is broken

Diphenhydramine Hydrochloride
Ethanamine, 2-(diphenylmethoxy)-N,N-dimethyl-, hydrochloride

Rx Only

CAS# 147-24-0

Net contents: 0.75 g
Repackaged by:
Fusion Pharmaceuticals, LLC
Camarillo, CA 93012

CS65-A1 rev 1

Do not use if safety seal is broken

Diphenhydramine Hydrochloride

Ethanamine, 2-(diphenylmethoxy)-N,N-dimethyl-, hydrochloride

Rx Only

CAS# 147-24-0
Net contents: 0.75 g

FUSION PHARMACEUTICALS LLC

Repackaged by:
Fusion Pharmaceuticals, LLC
Camarillo, CA 93012

CS65-A1 rev 1

Suspension Label

Do not use if safety seal is broken

Oral Suspension Vehicle
Sugar, dye, and paraben free

Ingredients: water, glycerin, xylitol, monoammonium glycyrrhizinate, pineapple flavor, xanthan gum, stevia powder, orange flavor, citric acid, sodium citrate, melatonin, potassium sorbate, sodium benzoate

Net Contents: 150 mL (5.1 fl oz)

Manufactured for:
Fusion Pharmaceuticals, LLC
Camarillo, CA 93012

CS66-A1 rev 1

Do not use if safety seal is broken

Oral Suspension Vehicle

Sugar, dye, and paraben free

Ingredients: water, glycerin, xylitol, monoammonium glycyrrhizinate, pineapple flavor, xanthan gum, stevia powder, orange flavor, citric acid, sodium citrate, melatonin, potassium sorbate, sodium benzoate

Net contents: 150 mL (5.1 fl oz)

FUSION PHARMACEUTICALS LLC

Manufactured for:
Fusion Pharmaceuticals, LLC
Camarillo, CA 93012

CS66-A1 rev 1

Instructions Insert

NDC 43093-104-01
Rx Only

FusePaq tm DICOPANOL tm
(diphenhydramine hydrochloride 5 mg/mL, oral suspension- kit)

FusePaq tm kits provide a convenient approach to rapidly create prescription medications, as all components are pre-measured. This kit is manufactures according to US FDA current Good Manufacturing Practice (cGMP).

Description:

This kit contains active and inactive bulk materials to create a diphenhydramine hydrochloride oral suspension. These instructions describe how to prepare 150 mL of oral suspension containing 5 mg/mL diphenhydramine hydrochloride. Other concentrations are possible. Exact strength of the resulting final

suspension must be defined by the prescriber.

Contents:

- 0.75 g diphenhydramine hydrochloride, USP
- 150 mL oral suspension vehicle (water, glycerin, xylitol, monoammonium glycyrrhizinate, pineapple flavor, xanthan gum, stevia powder, orange flavor, citric acid, sodium citrate, melatonin, potassium sorbate, sodium benzoate)

Instructions for the Pharmacist

Diphenhydramine hydrochloride, 5 mg/mL oral suspension

1 Remove and Inspect the Contents of the Kit

Ensure that the safety seals are present and intact on the diphenhydramine hydrochloride and oral suspension vehicle bottles. If the seals are not intact, do not use the kit.

2 Prepare for Combining

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

3 Transfer Diphenhydramine Hydrochloride to the Suspension Bottle

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

4 Complete the Combining Process

Insert the press-in bottle adaptor into the suspension bottle. Recap the suspension bottle. Shake well by inverting repeatedly several times.

5 Re-label the Resulting Final Suspension

Label the resulting final suspension per the pharmacy's standard practice. Remove or obscure the oral suspension vehicle label, since the label is no longer accurate once the resulting final suspension is completed.

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 at least eight

weeks, based upon real-time and accelerated stability studies.

Each lot of suspension vehicle is tested to meet microbial limits per USP Microbial Limit Test 61. In addition, the suspension vehicle formulation has passed the USP 51 Antimicrobial Effectiveness Test.

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

U.S. Patents Pending

Manufactured by:
Fusion Pharmaceuticals, LLC
768 Calle Plano
Camarillo, CA 93012

CS67-A1 rev 1

NDC 43093-104-01 **Rx only**

FusePaq™ DICOPANOL™

(diphenhydramine hydrochloride 5 mg/mL, oral suspension - kit)

FusePaq™ kits provide a convenient approach to rapidly create 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 bulk materials to create a diphenhydramine hydochloride oral suspension. These instructions describe how to prepare 150 mL of oral suspension containing 5 mg/mL diphenhydramine hydrochloride. Other concentrations are possible. Exact strength of the resulting final suspension must be defined by the prescriber.

Contents:

- 0.75 g diphenhydramine hydrochloride, USP
- 150 mL oral suspension vehicle (water, glycerin, xylitol, monoammonium glycyrrhizinate, pineapple flavor, xanthan gum, stevia powder, orange flavor, citric

acid, sodium citrate, melatonin, potassium sorbate, sodium benzoate)
- Press-in bottle adaptor for oral dispenser
- Oral dispenser
- Instructions

Instructions for the Pharmacist

Diphenhydramine hydrochloride, 5 mg/mL oral suspension

1 Remove and Inspect the Contents of the Kit

Ensure that the safety seals are present and intact on the diphenhydramine hydrochloride and oral suspension vehicle bottles. If the seals are not intact, do not use the kit.

2 Prepare for Combining

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

CS67-A1 rev 1

NDC 43093-104-01 **Rx only**

FusePaq™ **DICOPANOL™**

(diphenhydramine hydrochloride 5 mg/mL, in oral suspension - kit)

Instructions for the Pharmacist (continued)

3 Transfer Diphenhydramine Hydrochloride to the Suspension Bottle

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

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4 Complete the Combining Process

Insert the press-in bottle adaptor into the suspension bottle. Recap the suspension bottle. Shake well by inverting repeatedly several times.

5 Re-label the Resulting Final Suspension

Label the resulting final suspension per the pharmacy's standard practice. Remove or obscure the oral suspension vehicle label, since the label is no longer accurate once the resulting final suspension is completed.

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 at least eight weeks, based upon real-time and accelerated stability studies.

Each lot of suspension vehicle is tested to meet microbial limits per USP Microbial Limit Test <61>. In addition, the suspension vehicle formulation has passed the USP <51> Antimicrobial Effectiveness Test.

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

U.S. Patents Pending

Manufactured by:
Fusion Pharmaceuticals, LLC
768 Calle Plano
Camarillo, CA 93012

CS67-A1 rev 1

DICOPANOL
diphenhydramine hydrochloride kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43093-104

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43093-104-01	1 in 1 KIT		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, GLASS	0.75 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	0.75 g in 0.75 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		02/08/2010	

Part 2 of 2

ORAL SUSPENSION VEHICLE

suspension liquid

Product Information	
Route of Administration	ORAL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

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

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		02/08/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/08/2010	

Labeler - Fusion Pharmaceuticals LLC (021420944)

Registrant - Fusion Pharmaceuticals LLC (021420944)

Establishment

Name	Address	ID/FEI	Business Operations
California Pharmaceuticals LLC		021420944	manufacture(43093-104)

Revised: 11/2015 Fusion Pharmaceuticals LLC