RANITIDINE HYDROCHLORIDE ORAL SUSPENSION KIT- ranitidine 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.

Ranitidine Hydrochloride Oral Suspension
Pineapple/Orange Oral Suspension Kit
Repackaged 70332-109

Instructions for Preparation

Page 1

Page 2

NDC 70332-109-01

For Prescription Compunding Only

Rx only

Ranitidine Hydrochloride Oral Suspension

Ranitidine hydrochloride 25.0mg/mL [equivalent to 22.4 mg/mL rantidine]

Pineapple/Orange oral suspension - kit

Ranitidine Hydrochloride Oral Suspension 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 250mL of a ranitidine hydochloride Pineapple/Orange oral suspension containing 25.0 mg/mL ranitidine Hydrochloride [equivalent to 22.4 mg/mL ranitidine]. **This kit may only be used for prescriptioncompounding 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:

- 6.4 ranitidine hydrochloride USP [equivalent to 5.7 g ranitidine]

- 250mL Pineapple/Orange oral suspension vehicle (purified water, glycerin, xylitol, monoammoniumium glycyrrhizinate, pineapple flavor,

orange flavor, potassium sorbate, xanthan gum, sodium benzoate, citric acid, sodium

citrate)

- 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 ranitidine hydrochloride and 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 ranitidine hydrochloride bottle.

3 Transfer Ranitidine Hydrochloride to the Pineapple/Orange Suspension Bottle

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

4 Completing the Compounding Process

Insert the press-in bottle adaptor into the Pineapple/Orange suspension bottle that now contains the renitidine hydrochloride. Recap the Pineapple/Orange suspension bottle. Mix well by inverting repestedly several times. Visually ensure that all contents are dissolved.

5 Re-label the Resulting Final Suspension

Label the resulting final suspension as required for prescription products. Ensure that the original Pineapple/Orange 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 mixed suspension between 2-8°C (36-46°F). The resulting final suspension is stable for up to eight weeks, based upon real-time and accelerated stability studies.

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

U.S. Patents Pending

Repackaged and Distributed by:

California Pharmaceuticals LLC

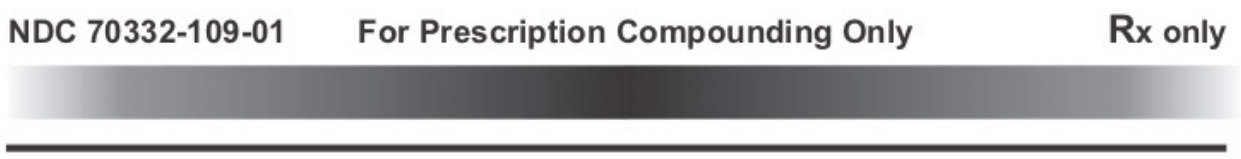
768 Calle Plano

Camrillo, CA 93012

California

PHARMACEUTICALS LLC

CS43-A1 rev 3



Ranitidine hydrochloride 25.0 mg/mL [equivalent to 22.4 mg/mL ranitidine]
Pineapple/Orange oral suspension - kit

California Pharmaceutical 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 250mL of a ranitidine hydochloride Pineapple/Orange oral suspension containing 25.0 mg/mL ranitidine hydrochloride [equivalent to 22.4 mg/mL ranitdine]. **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:
- 6.4 g ranitidine hydrochloride USP [equivalent to 5.7 g ranitidine]
- 250 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 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 ranitidine hydrochloride and 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 ranitidine hydrochloride bottle.

NDC 70332-109-01 **For Prescription Compounding Only** **Rx only**

Pharmacist Instructions for Preparation

3 Transfer Ranitidine Hydrochloride to the Pineapple/Orange Suspension Bottle

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

4 Complete the Combining Process

Insert the press-in bottle adaptor into the Pineapple/Orange suspension bottle that now contains the ranitidine hydrochloride ingredient. Recap the Pineapple/Orange suspension bottle. Mix well by inverting repeatedly several times. Visually ensure that all contents are dissolved.

5 Re-label the Resulting Final Suspension

Label the resulting final suspension as required for prescription products. Ensure that the original Pineapple/Orange 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 mixed suspension between 2-8°C (36-46°F). The resulting final suspension is stable for up to eight weeks, based upon real-time and accelerated stability studies.

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

U.S. Patents Pending

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California Pharmaceuticals LLC
768 Calle Plano
Camarillo, CA 93012

Ranitidine Hydrochloride Product Label

Do not use if safety seal is broken

Ranitidine Hydrochloride

1, 1-Ethenediamine, N-[2-[[[5-[(dimethylamino)methyl]-2furanyl]-methyl]thio]ehtyl]-N-methyl-2-nitro, monohydrochloride

CAS # 66357-59-3

Net contents: 6.4 g

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Camarillo, CA 93012

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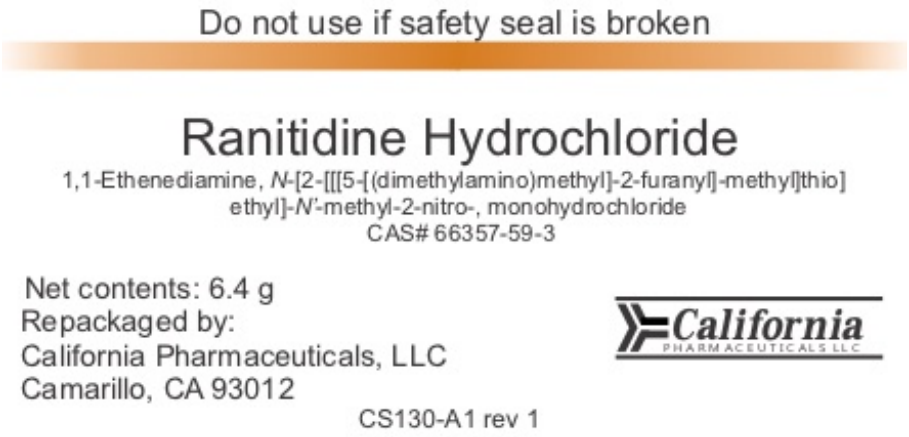
PHARMACEUTICALS

CS130-A1 rev 1



Oral Suspension Label

Do not use if safety seal is broken

Pineapple/Orange Oral Suspension Vehicle

Sugar, dye, and paraben free

Ingredients: purified water, glycerin, xylitol, monoammoniumium glycyrrhizinate, pineapple flavor, orange flavor, potassium sorbate, xanthan gum, sodium benzoate, citric acid, sodium citrate

Net contents: 250 mL (8.4 fl oz)

Manufactured for:

California Pharmaceuticals LLC

Camarillo, Ca 3012

California

PHARMACEUTICALS LLC

CS36-A-1 rev 2

Ranitidine Hydrochloride Oral Suspension Pineapple/Orange Oral Suspension Kit Label

NDC 70332-109-01

Rx only

Ranitidine Hydrochloride Oral Suspension and Pineapple/Orange Oral Suspension Kit

(ranitidine hydrochloride 25.0 mg/mL [equivalent to 22.4 mg/mL rantidine],

in a Pineapple/Orange oral suspension kit) Histamine-2 blocker

Description:

This kit contains active and inactive materials to prepare 250mL of a ranitidine hydochloride Pineapple/Orange oral suspension containing 25.0 mg/mL ranitidine hydrochloride [equivalent to 22.4 mg/mL ranitidine]. **This kit may only be used for prescriptioncompounding 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:

- 6.4 ranitidine hydrochloride USP [equivalent to 5.7 g ranitidine]

Inactive Ingredients:

- 250mL Pineapple/Orange oral suspension vehicle (purified water, glycerin, xylitol, monoammoniumium glycyrrhizinate, pineapple flavor,

orange flavor, potassium sorbate, xanthan gum, sodium benzoate, citric acid, sodium

citrate)

- Press-in bottle adaptor

- Oral dispenser

- Instructions

U. S. Patents Pending

Do not use if safety seal is broken

Store kit at room temperature,

15-30°C (59-86°F).

California

PHARMACEUTICALS LLC

Repackaged and Distributed by:

California Pharmaceuticals, LLC

768 Calle Plano

Camarillo, Ca 93012

CS129-A1 rev 2

RANITIDINE HYDROCHLORIDE ORAL SUSPENSION KIT

ranitidine hydrochloride kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70332-109

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70332-109-01	1 in 1 KIT	01/02/2017	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	6.4 g
Part 2	1 BOTTLE	250 mL

Part 1 of 2

RANITIDINE HYDROCHLORIDE

ranitidine hydrochloride powder, for suspension

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7)	RANITIDINE	6.4 g in 6.4 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		6.4 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 2

ORAL VEHICLE

oral vehicle suspension

Product Information	
Route of Administration	ORAL

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

GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	PINEAPPLE (PINEAPPLE;ORANGE)	**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			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/02/2017	

Labeler - California Pharmaceuticals, LLC (021420944)

Registrant - California Pharmaceuticals, LLC (021420944)

Establishment

Name	Address	ID/FEI	Business Operations
California Pharmaceuticals, LLC		021420944	repack(70332-109) , manufacture(70332-109)

Revised: 1/2018 California Pharmaceuticals, LLC