FANATREX- gabapentin
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.

Fanatrex

Fanatrex - Pharmacist Instructions Page 1

NDC 70332-105-01 For Prescription Compounding Only

RapidPaq™ FANATREX™

(gabapentin 25 mg/mL, in a Strawberry/Marshmallow/Banana oral susp

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

Description:
This kit contains active and inactive materials to prepare 420 mL of a oral suspension containing 25 mg/mL gabapentin. This kit may only prescription compounding by an appropriate licensed medical p response to a physician's prescription, to create a medication ta specialized needs of an individual patient.

Contents:
- 10.8 g gabapentin, USP
- 420 mL oral suspension vehicle (purified water, strawberry flavor, glycerin, acesulfame potassium, banana flavor, xathan gum, potas monoammonium glycyrrhizinatre, sodium saccharin, sodium benz citric acid)
- Disposable funnel
- Press-in bottle adaptor
- Oral dispenser
- Instructions

Pharmacist Instructions for Preparatic
Gabapentin, 25 mg/mL oral suspension

1 Remove and Inspect the Contents of the Kit

Remove kit contents. Ensure that seals are present and intact on the and Strawberry/Marshmallow/Banana oral suspension vehicle bottles intact, do not use the kit.

2 Prepare for Compounding

Wear gloves and eye protection during combining operations. Remov from the strawberry/marshmallow/bananoral suspension bottle. Breal remove the cap from the gabapentin bottle.

Fanatrex - Pharmacist Instructions Page 2

NDC 70332-105-01 For Prescription Compounding Only

℞ Rx Only FANATREX™

(gabapentin 25 mg/mL, in a Strawberry/Marshmallow/Banan oral sus

Pharmacist Instruction for Prepara

3 Transfer Gabapentin to the Strawberry/Marshmallow/ Suspension Bottle

Uncap the Strawberry/Marshmallow/Banana suspension bottle. Using carefully transfer the gabapentin powder to the suspension bottle. Ca and mix thoroughly by inverting and shaking until all contents are diss suspension bottle. Pour a small amount of the mixed suspension bac bottle. Cap the gabapentin bottle and shake to ensure that all residua dissolved. Pour the liquid through the funnel into the suspension bottl and gabapentin powder bottle.

4 Complete the Compounding Process

Insert the press-in bottle adaptor into the suspension bottle. Recap th bottle. Shake well by inverting repeatedly several times. Visually enst are dissolved.

5 Re-label the Resulting Final Suspension

Label the resulting final suspension as required for prescription produ
original oral suspension vehicle label is removed or obscured, since t
is no longer accurate once the resulting final suspension is completec
bottle need to be shaken well before taken as directed by the medica

Store the unused kit at room temperature of 15-30°C (59-86°F). Onc
store the resulting final suspension between 15-30°C (59-86°F). The
suspension is stable for a up to of eight weeks.

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

U.S. Patents Pending

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

CS75-A1 rev 3

Gabapentin - Label

Fanatex - Flavor Label

Fanatrex - Package Label.Principal Display

Fanatrex - Principal package label

NDC 70332-105-01 Rx only

RapidPaq™ **Strawberry/Marshmallow/Banana 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

Fanatrex™

(gabapentin 25 mg/mL, in Strawberry/Marshmallow/Banana oral suspension-kit)

Anticonvulsant

Description:
This kit contains active and inactive materials to prepare 420 mL of a gabapentin strawberry/marshmallow/banana oral suspension containing 25 mg/mL gabapentin. **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:
- 10.8 g gabapentin, USP

Inactive Ingredients:
- 420 mL oral suspension vehicle (purified water, strawberry flavor, marshmallow flavor, glycerin, acesulfame potassium, banana flavor, xathan gum, potassium sorbate, monoammonium glycyrrhizinate, sodium saccharin, sodium benzoate, citric acid)
- Disposable funnel
- Press-in bottle adaptor
- Oral dispenser
- Instructions

70332-105-01

U. S. Patents Pending

Do not use if safety seal is broken

CS95-A1 rev 3

FANATREX

gabapentin kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70332-105

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70332-105-01	1 in 1 KIT		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, GLASS	10.8 g
Part 2	1 BOTTLE, PLASTIC	420 mL

Part 1 of 2

GABAPENTIN

gabapentin powder, for suspension

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GABAPENTIN (UNII: 6CW7F3G59X) (GABAPENTIN - UNII:6CW7F3G59X)	GABAPENTIN	10.8 g in 10.8 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		10.5 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 2 of 2

ORAL SUSPENSION VEHICLE

suspension liquid

Product Information	
Route of Administration	ORAL

Inactive Ingredients	
Ingredient Name	**Strength**
STEVIA LEAF (UNII: 6TC6NN0876)	
WATER (UNII: 059QF0KO0R)	
N-ACETYLGLUCOSAMINE (UNII: V956696549)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
GLYCYRRHIZIN, AMMONIATED (UNII: 3VRD35U26C)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
BANANA (UNII: 4AJZ4765R9)	
STRAWBERRY (UNII: 4J2TY8Y81V)	
ALTHAEA OFFICINALIS LEAF (UNII: E2QQV92338)	
GLYCERIN (UNII: PDC6A3C0OX)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1		420 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(70332-105)

Revised: 1/2016 California Pharmaceuticals, LLC