

**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.*

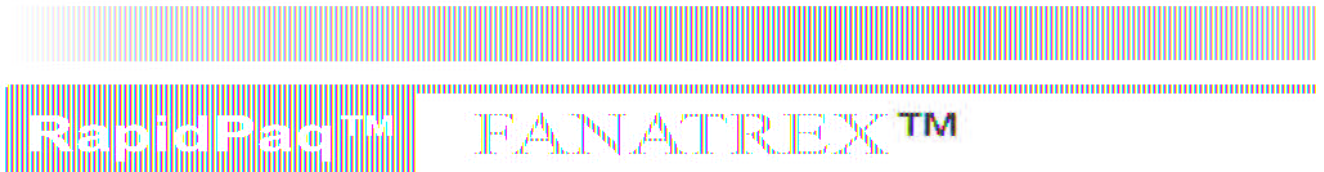
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**Fanatrex**

**Fanatrex - Pharmacist Instructions Page 1**

NDC 70332-105-01

For Prescription Compounding Only



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

*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 glycyrrhizinate, 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 Strawberry/Marshmallow/Banana oral suspension vehicle bottles. If the Strawberry/Marshmallow/Banana oral suspension vehicle bottles are not intact, do not use the kit.

## 2 Prepare for Compounding

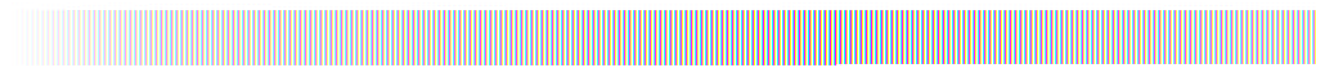
Wear gloves and eye protection during combining operations. Remove the cap from the Strawberry/Marshmallow/Banana oral suspension bottle. Break the cap from the gabapentin bottle.

CS75-A1 rev 3

### Fanatrex - Pharmacist Instructions Page 2

NDC 70332-105-01

For Prescription Compounding Only



**RapidPac™**

**FANATREX™**

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

## Pharmacist Instruction for Preparation

### 3 Transfer Gabapentin to the Strawberry/Marshmallow/Banana Suspension Bottle

Uncap the Strawberry/Marshmallow/Banana suspension bottle. Using a funnel, carefully transfer the gabapentin powder to the suspension bottle. Cap and mix thoroughly by inverting and shaking until all contents are dissolved in the suspension bottle. Pour a small amount of the mixed suspension back into the gabapentin bottle. Cap the gabapentin bottle and shake to ensure that all residual powder is dissolved. Pour the liquid through the funnel into the suspension bottle and cap the gabapentin powder bottle.

### 4 Complete the Compounding Process

Insert the press-in bottle adaptor into the suspension bottle. Recap the gabapentin bottle. Shake well by inverting repeatedly several times. Visually ensure that all powder is dissolved.

## 5 Re-label the Resulting Final Suspension

Label the resulting final suspension as required for prescription product. Once the original oral suspension vehicle label is removed or obscured, since it is no longer accurate once the resulting final suspension is complete, 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 the resulting final suspension is complete, 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 the final 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



**Strawberry/Marshmallow/Banana  
Oral Suspension Kit**

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



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**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70332-105
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**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**

<b>Route of Administration</b>	ORAL
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**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
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**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
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1	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
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### 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