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

DESCRIPTION

NDC 43093-105-01

Rx only

FusePaq™

FANATREX™

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

FusePaq™ 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 Practices (cGMP).

Description:

This kit contains active and inactive bulk materials to prepare 420 mL of a gabapentin oral suspension containing 25 mg/mL gabapentin. **This kit may only be used for the extemporaneous mixing 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.**

Contents:

- 10.5 g gabapentin, USP
- 420 mL oral suspension vehicle (water, banana flavor, N-acetyl-D-glucosamine, strawberry flavor, marshmallow flavor, glycerin, stevia powder, acesulfame potassium, xanthan gum, monoammonium glycyrrhizinate, sodium saccharin, sodium benzoate, potassium sorbate, dibasic sodium phosphate)
- Disposable funnel
- Press-in bottle adaptor for oral dispenser
- Oral dispenser
- Instructions

SUGGESTED PREPARATION

Suggested Preparation
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 gabapentin and oral suspension vehicle bottles. If the seals are not intact, do not use the kit.

2 Prepare for Mixing

Wear gloves and eye protection during mixing operations. Remove the seal from the oral suspension bottle. Break the seal and remove the cap from the gabapentin bottle.

3 Transfer Gabapentin to the Suspension Bottle

Uncap the suspension bottle. Using the included funnel, carefully transfer the gabapentin powder to the suspension bottle. Cap the suspension bottle and mix thoroughly by inverting and shaking until all contents are dissolved. Uncap 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 gabapentin has been dissolved. Pour the liquid through the funnel into the suspension bottle. Discard the funnel and gabapentin powder bottle.

4 Complete the Mixing Process

Insert the press-in bottle adaptor into the suspension bottle. Recap the suspension bottle. Mix well by inverting repeatedly several times. Visually ensure that all contents are dissolved.

5 Re-label the Suspension

Label the mixed suspension as required for prescription products. Ensure that the original oral suspension vehicle label is removed or obscured, since the original label is no longer accurate once the suspension is prepared.

Store the unused kit at room temperature of 15-30°C (59-86°F). Once prepared, store the mixed suspension between 15-30°C (59-86°F). The mixed 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

CS75-A1 rev 0

DRUG BOTTLE LABEL

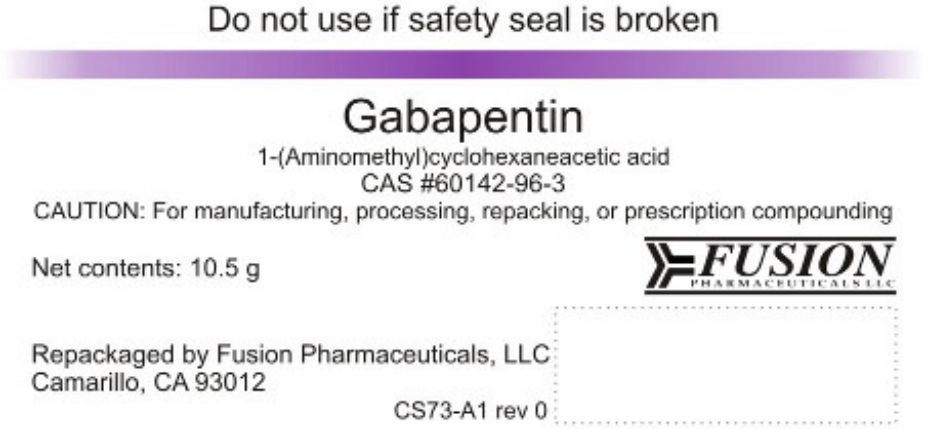
Do not use if safety seal is broken

Gabapentin
1-(Aminomethyl)cyclohexaneacetic acid
CAS #60142-96-3
CAUTION: For manufacturing, processing, repacking, or prescription compounding

Net contents: 10.5 g

Repackaged by Fusion Pharmaceuticals, LLC
Camarillo, CA 93012

CS73-A1 rev 0



SUSPENSION BOTTLE LABEL

Do not use if safety seal is broken
For Prescription Compounding Only

Oral Suspension Vehicle
Dye and paraben free

Ingredients: water, banana flavor, N-acetyl-D-glucosamine, strawberry flavor, marshmallow flavor, glycerin, stevia powder, acesulfame potassium, xanthan gum, monoammonium glycyrrhizinate, sodium saccharin, potassium sorbate, sodium benzoate, dibasic sodium phosphate

Net Contents: 420 mL (14.2 fl oz)

Manufactured for:
Fusion Pharmaceuticals, LLC
Camarillo, CA 93012

CS74-A1 rev 0

Carton Box Label

Do not use if safety seal is broken

NDC 43093-105-01

Rx only

FusePaq™ Kit for Oral Suspension
Fanatrex™
(gabapentin 25 mg/mL, in oral suspension - kit)

Description:
This kit contains active and inactive bulk materials to prepare 420 mL of a gabapentin oral suspension containing 25 mg/mL gabapentin. **This kit may only be used for the extemporaneous mixing 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.**

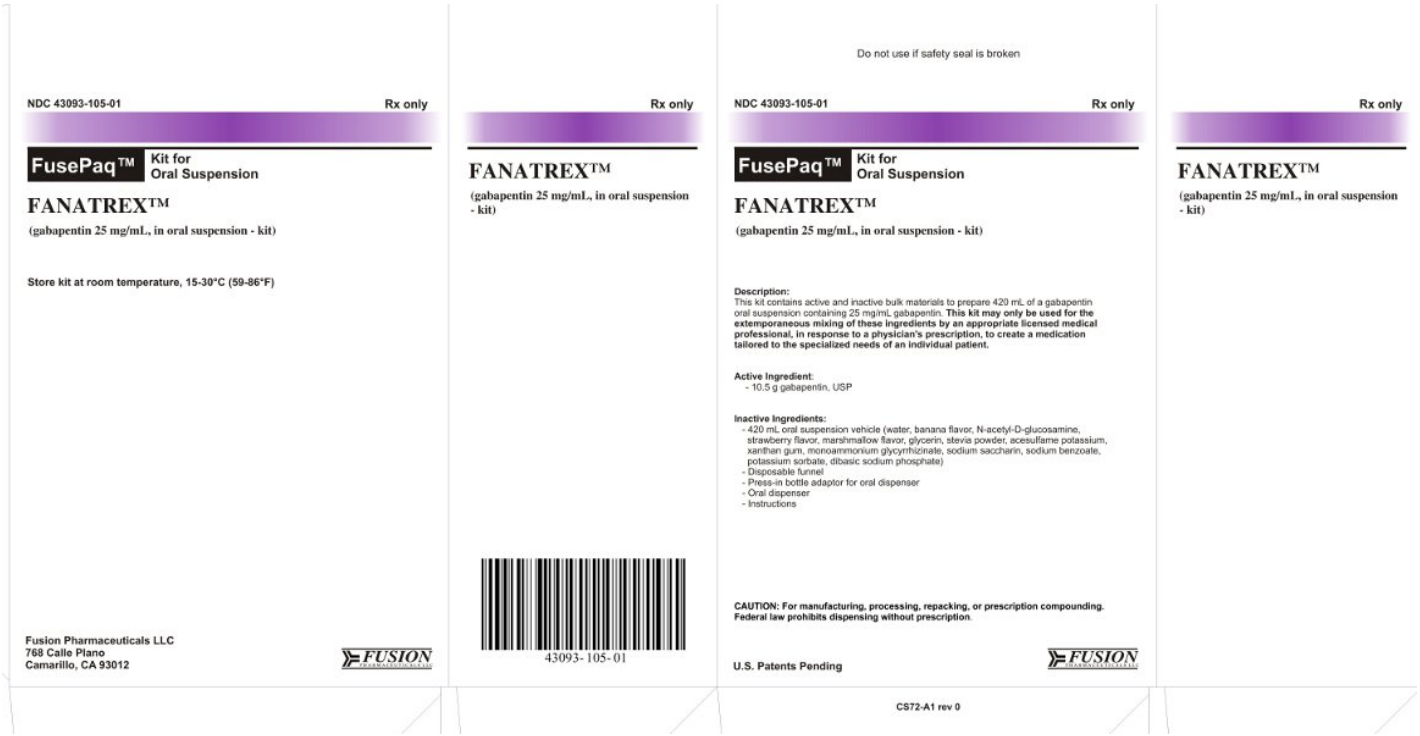
Active Ingredient:
- 10.5 g gabapentin, USP

Inactive Ingredients:
- 420 mL oral suspension vehicle (water, banana flavor, N-acetyl-D-glucosamine, strawberry flavor, marshmallow flavor, glycerin, stevia powder, acesulfame potassium, xanthan gum, monoammonium glycyrrhizinate, sodium saccharin, potassium sorbate, sodium benzoate, dibasic sodium phosphate)
- Disposable funnel
- Press-in bottle adaptor for oral dispenser
- Oral dispenser
- Instructions

CAUTION: For manufacturing, processing, repacking, or presciption compounding. Federal law prohibits dispensing without prescription.

U.S. Patents Pending

CS72-A1 rev 0



FANATREX

gabapentin kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43093-105

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43093-105-01	1 in 1 KIT		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, GLASS	10.5 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	10.5 g in 10.5 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		05/15/2010	

Part 2 of 2

ORAL SUSPENSION VEHICLE

suspension liquid

Product Information	
Route of Administration	ORAL

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

Packaging			
#	**Item**	**Marketing Start**	**Marketing End**

#	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		05/15/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/15/2010	

Labeler - California Pharmaceuticals LLC (021420944)

Establishment

Name	Address	ID/FEI	Business Operations
California Pharmaceuticals LLC		021420944	manufacture(43093-105)

Revised: 11/2015 California Pharmaceuticals LLC