KETOPHENE- ketophene
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.

KETOPHENE - 70332-101

Instructions for Preparation
Page 1
Page 2

NDC 70332-101-01 For Prescription Compounding Only Rx only

RapidPaq™ Ketophene™

(20% Ketoprofen topical cream kit)

RapidPaq™ 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 materials to prepare approximately 167 grams of ketoprofen topical cream. **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:

- 33.5 g Ketoprofen, USP

Inactive Ingredients:

- 100 g RapidPaq Cream Base (D.I Water, Cetearyl Alcohol, Cyclomethicone, Polysorbate-60, Sorbitol, Phenoxyethanol(and)ethylhexlglycerin,

Tocopheryl Acetate, Aloe Barbadensis, Disodium EDTA,)

- 33.5 g ethoxy diglycol

- Spatula

-Instructions

Pharmacist instructions for Preparation

1 Remove and Inspect the Contents of the Kit

Ensure that all components are present. Ensure that the safety seals are present on the Ketoprofen, ethoxy diglycol and RapidPaq Cream Base. If components are missing or not intact, do not use the kit.

2 Prepare for Mixing

Wear gloves and eye protection during mixing operations. Remove cap and seal from the RapidPaq Cream Base. Break the seal and remove the cap from the Ketoprofen and ethoxy diglycol.

3 Dissole the Ketoprofen

Transfer approximately 2/3 of the ethoxy diglycol to the Ketoprofen jar. With the supplied spatula, mix them together until they are mostly dissolved. Transfer the Ketoprofen mix to the jar of RapidPaq Cream Base. Transfer the remaining 1/3 of ethoxy diglycol to the Ketoprofen jar and repeat the mixing

process. transfer the remaining Ketoprofen mix to the jar of RapidPaq Cream Base.

4 Complete the Mixing Process

Using the spatula, mix the RapidPaq Crean base jar that now contains the ethoxy diglycol and Ketoprofrn ingredients thoroughly for about 2 minutes or until fully dissolved.

5 Relabel the Resulting Cream

Label the resulting topical cream as required for prescription products. Ensure that the original RapidPaq Cream Base label is removed or obscured, since the original label is no longer accurate once the cream is prepared.

Discard the spatula.

Store the unused kit at room temperature of 15-30°C (59-86°F). Once prepared, store the topical cream between 15-30°C (59-86°F). The resulting final topical cream is stable for up to eight weeks.

U.S. Patents Pending

Repacked and Distributed by:

California Pharmaceuticals, LLC

768 Calle Plano

Camarillo, CA 93012

CS113-A1 rev 2

California

PHARMACEUTICALS LLC

NDC 70332-101-01 For Prescription Compounding Only **Rx only**

RapidPaq™ Ketophene™

(20% Ketoprofen topical cream kit)

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- 33.5 g ethoxy diglycol
- Spatula
- Instructions

Pharmacist Instructions for Preparation

1 Remove and Inspect the Contents of the Kit

Ensure that all components are present. Ensure that the safety seals are present on the Ketoprofen, ethoxy diglycol and RapidPaq Cream Base. If components are missing or not intact, do not use the kit.

2 Prepare for Mixing

Wear gloves and eye protection during mixing operations. Remove cap and seal from the RapidPaq Cream Base. Break the seal and remove the cap from the Ketoprofen and ethoxy diglycol.

RapidPaq™ Ketophene™

(20% Ketoprofen topical cream kit)

Pharmacist
Instructions for Preparation (continued)

3 Dissolve the Ketoprofen

Transfer approximately 2/3 of the ethoxy diglycol to the Ketoprofen jar. With the supplied spatula, mix them together until they are mostly dissolved. Transfer the Ketoprofen mix to th jar of RapidPaq Cream Base. Transfer the remaining 1/3 of ethoxy diglycol to the Ketoprofen jar and repeat the mixing process. Transfer the remaining Ketoprofen mix to the jar of RapidPaq Cream Base.

4 Complete the Mixing Process

Using the spatula, mix the RapidPaq Cream Base jar that now contains the ethoxy diglycol and Ketoprofen ingredients thoroughly for about 2 minutes or until fully dissolved.

5 Relabel the Resulting Cream

Label the resulting topical cream as required for prescription products. Ensure that the original RapidPaq Cream Base label is removed or obscured, since the original label is no longer accurate once the cream is prepared.

Discard the spatula.

Store the unused kit at room temperature of 15-30°C (59-86°F). Once prepared, store the topical cream between 15-30°C (59-86°F). The resulting final topical cream is stable for up to eight weeks.

U.S. Patents Pending

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

California PHARMACEUTICALS LLC

RapidPaq™ Cream Base product label

Do not use if seal is broken

California

PHARMACEUTICALS LLC

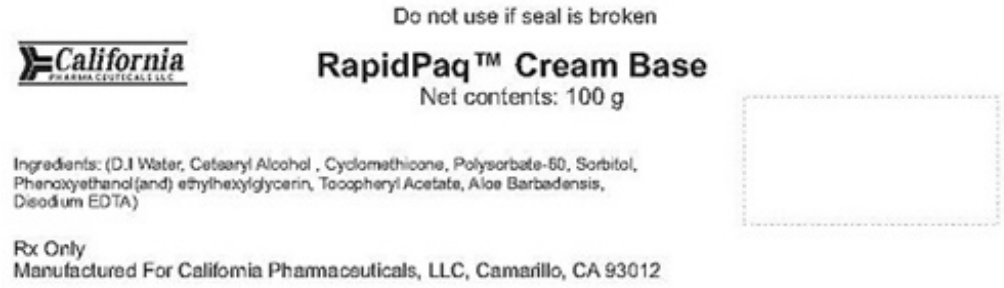
RapidPaq™ Cream Base

Net contents: 100g

Ingredients: (D.I Water, Cetearyl Alcohol, Cyclomethicone, Polysorbate-60, Sorbitol, Phenoxyethanol(and)ethylhexlglycerin, Tocopheryl Acetate, Aloe Barbadensis, Disodium EDTA

RX Only

Manufactured For California Pharmaceuticals, LLC, Camarillo, CA 93012



Ethoxy Diglycol product label

Do not use if safety seal is broken

Ethoxy Diglycol

Diethyl Glycol Monoethly Ether

CAS # 111-90-0

Net contents 33.5 g

Rx Only

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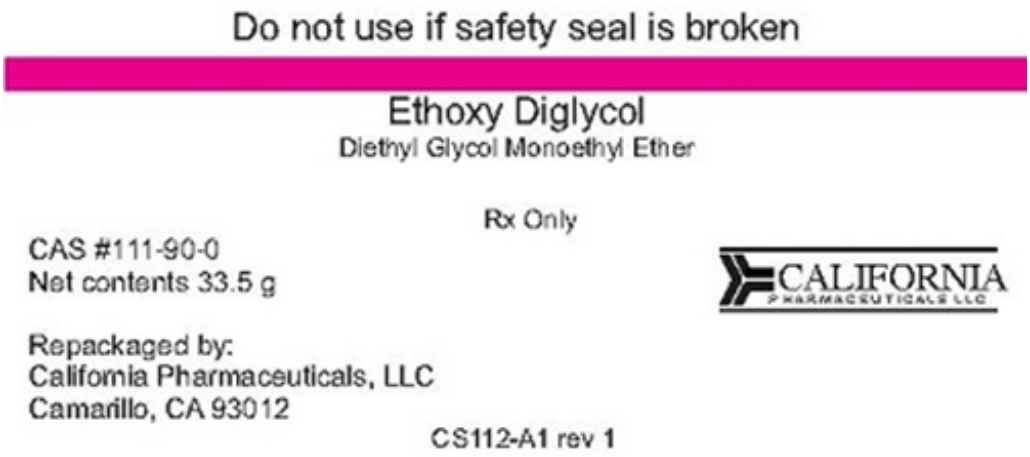
California Pharmaceuticals, LLC

Camarillo, Ca 93012

California

PHARMACEUTICALS LLC

cs112-A1 rev 1



Ketoprofen, USP product label

Do not use if seal is broken

Ketoprofen, USP

C16H14O3 CAS # 22071-15-4

Net contents: 33.5 g

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RX Only

Repackaged by California Pharmaceuticals, LLC, Camarillo, CA 93012

CS110-A1 rev 1

Ketophene Kit product label

NDC 70332-101-01

Rx only

RapidPaq™

Kit for Topical Cream

KETOPHENE™

(20% ketoprofen cream kit) Non-Steroid Anti-Inflammatory

Store kit at room temperature,

15-30°C (59-86°F0

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Inactive Ingredients:

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Tocopheryl Acetate, Aloe Barbadensis, Disodium EDTA)

- 33.5g ethoxy diglycol

- Spatula

- Instrustions

U. S. Patents Pending

Do not use if safety seal is broken

California

PHARMACEUTICALS

Repacked and Distributed By:

California Pharmaceuticals, LLC

768 Calle Plano

Camarillo, CA 93012

CS114-A1 rev 2

KETOPHENE

ketophene kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70332-101

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70332-101-01	1 in 1 KIT	01/01/2016	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	33.5 g
Part 2	1 BOTTLE	33.5 g
Part 3	1 JAR	100 g

Part 1 of 3

ETHOXYDIGLYCOL

diethylene glycol monoethyl ether liquid

Product Information	
Route of Administration	TOPICAL

Inactive Ingredients	
Ingredient Name	**Strength**
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		33.5 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			

Part 2 of 3

KETOPROFEN

ketoprofen powder, for suspension

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
KETOPROFEN (UNII: 90Y4QC304K) (KETOPROFEN - UNII:90Y4QC304K)	KETOPROFEN	33.5 g in 33.5 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		33.5 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			

Part 3 of 3

RAPIDPAQ CREAM BASE

rapidpaq cream base cream

Product Information	
Route of Administration	TOPICAL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SORBITOL (UNII: 506T60A25R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		100 g in 1 JAR; 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		01/01/2016	

Labeler - California Pharmaceuticals, LLC (021420944)

Registrant - California Pharmaceuticals, LLC (021420944)

Establishment

Name	Address	ID/FEI	Business Operations
California Pharmaceuticals, LLC		021420944	manufacture(70332-101) , repack(70332-101)

Revised: 7/2016 California Pharmaceuticals, LLC