VOPAC - KETOPROFEN, LIDOCAINE HYDROCHLORIDE PAC- ketoprofen
Sircle Laboratories, 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.

Vopac™ Topical Cream Compounding Pac

Preparation Instructions

Lidocaine HCL 2%, Ketoprofen 10%

FOR PRESCRIPTION COMPOUNDING ONLY

DESCRIPTION

Each Vopac Cream Compounding Pac provides 2.48 grams of micronized Lidocaine HCL USP, 11.050 grams of Ketoprofen USP, 12.47 ml of Lecithin Organogel USP and 88 grams of base cream. The resulting mixture is intended for topical use.

COMPOUNDING DIRECTIONS

TO THE PHARMACIST

Pack Components: 1 color coded red label bottle of 2.48 g of Lidocaine Hcl, 2 color coded yellow label bottles of 5.525 g of Ketoprofen, 1 tube of 88 g Base, 1 mixing jar of pre-weighed Lecithin Organogel, and 1 sterile stirring stick.

Base Cream	88.0 grams
Ketoprofen, USP	11.05 grams
Lidocaine HCL, USP	2.48 grams
Lecithin Organogel	12.47 ml
SIZE	114 grams

Prior to compounding, store Vopac Cream Compounding Preparation Pack at room temperature between 20-25 degrees C (68-77 degrees F).

Based on real time controlled room temperature and humidity testing, Vopac Cream finished compounding preparation product is stable for at least 30 days[1]

Vopac Cream Compounding Preparation meets the requirements for total aerobic microbial count of not more than 100 cfu/mL, as well as for the absence of the specified microorganisms *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella spp*. when tested as described in the current USP under <61> Microbial Enumeration Tests and <62> Tests for Specified Microorganisms. Vopac Cream Compounding Preparation suspension also meets the requirements as described in the current USP under <51> Antimicrobial Effectiveness Testing for Category 2 products.

For external use only: Avoid contact with eyes. Keep container tightly closed. Keep out of the reach of children. Compounded product, as dispensed, is ***stable for at least 30 days*** *Certificate of analysis on file

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1 Data and documentation on file

Compounding Directions

Important Prior to dispensing: Mixing Jar includes Lecithin liquid inside. DO NOT SPILL

Lecithin liquid is inside the mixing jar.

DO NOT SPILL when opening.

1. Open **"Mixing Jar" (mixing jar has Lecithin liquid inside). Be careful not to spill the contents while mixing.**
2. Tap the top and bottom of the **"Lidocaine HCL"** bottle. Open the bottle and empty the Lidocaine HCL into the Lecithin mixing jar and mix.
3. Tap the top and bottom of the **"Ketoprofen"** bottles. Open both bottles (2 bottles) and empty the Ketoprofen into the Lecithin mixing jar.
4. Stir gently with the enclosed stirrer provided for approximately 20 – 30 seconds until powders are wet and paste like in appearance. The appropriate quantities of powders have been packaged in each bottle to deliver the required dosage of each drug. Residual quantities remaining in the bottles after emptying need not be rinsed out.
5. Gradually add the tube of **"Base Cream"** to the mixing jar while stirring. Mix until homogeneous in appearance.
6. Add prescription label to the mixing jar and provide to patient.

Recommended Administration and Dosage

Apply thin layer (approximately 1/4 tsp) of mixed cream over specific site area every 4-6 hours or as needed.

Patent Pending
NDC #51021-880-14
Rx ONLY
Manufactured for & Marketed by: Sircle Laboratories, LLC, Madison, MS 39110

VOPAC TOPICAL CREAM COMPOUNDING PAC – lidocaine hydrochloride, ketoprofen

PRINCIPAL DISPLAY PANEL - Kit Carton Label

Keep This End Upright

Compounding Pack for Prescription Compounding Only
****Pharmacist/Physician** **Mixing Instructions Inside****

NDC 51021-880- 14

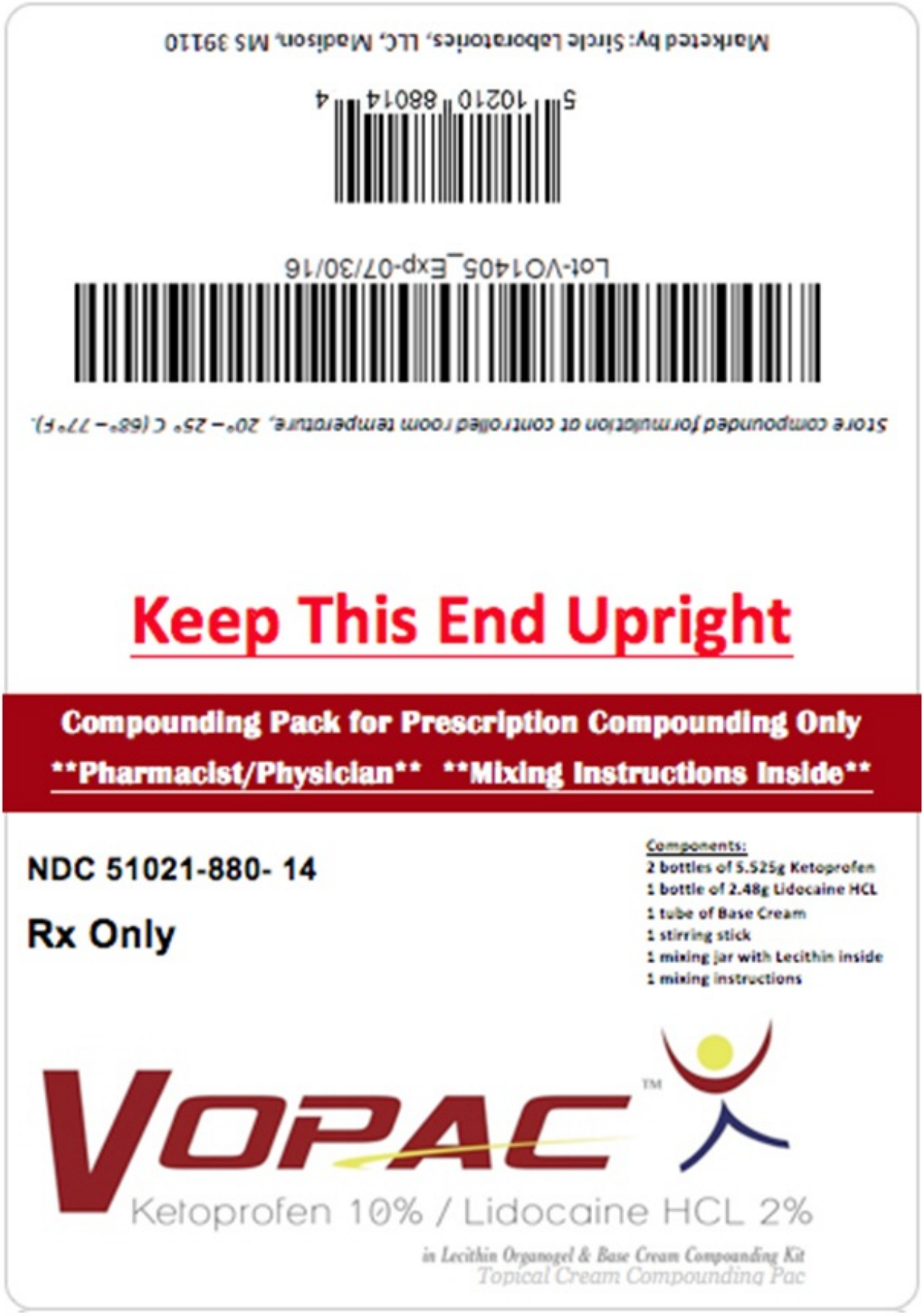
Rx Only

Components:
2 bottles of 5.525g Ketoprofen
1 bottle of 2.48g Lidocaine HCL
1 tube of Base Cream
1 stirring stick
1 mixing jar with Lecithin inside
1 mixing instructions

VOPAC™

Ketoprofen 10% / Lidocaine HCL 2%

Topical Cream Compounding Pac



VOPAC - KETOPROFEN, LIDOCAINE HYDROCHLORIDE PAC

ketoprofen kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51021-880

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51021-880-14	1 in 1 CARTON		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 TUBE	88 g
Part 2	1 BOTTLE, PLASTIC	2.48 g
Part 3	2 BOTTLE, PLASTIC	11.05 g
Part 4	1 JAR	12.47 mL

Part 1 of 4

BASE CREAM

base cream for suspension

Product Information			
Route of Administration	TOPICAL	**DEA Schedule**	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		88 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		03/01/2015	

Part 2 of 4

LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride powder, for suspension

Product Information			
Route of Administration	TOPICAL	**DEA Schedule**	

Inactive Ingredients	
Ingredient Name	**Strength**
Lidocaine Hydrochloride (UNII: V13007Z41A)	2.48 g in 2.48 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		2.48 g 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		03/01/2015	

Part 3 of 4

KETOPROFEN

ketoprofen powder, for suspension

Product Information			
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Ketoprofen (UNII: 90Y4QC304K) (Ketoprofen - UNII:90Y4QC304K)	Ketoprofen	5.525 g in 11.05 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		5.525 g 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		03/01/2015	

Part 4 of 4

LECITHIN ORGANOGEL

egg phospholipids for suspension

Product Information

Route of Administration	TOPICAL	DEA Schedule	

Inactive Ingredients

Ingredient Name	Strength
Egg Phospholipids (UNII: 1Z74184RGV)	12.47 mL in 12.47 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		12.47 mL 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		03/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		03/01/2015	

Labeler - Sircle Laboratories, LLC (962175621)