VONAFLEX- lidocaine lotion lotion
Cymbiotics, Inc

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.

CY15-Vonaflex

Active Ingredient

Lidocaine 4%

Uses

For temporary relief of pain & inflammation

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Directions

Use only as directed. Adults & children 12 years or older: apply evenly to affected area not more than 3-4 x daily. For children under 12 years, consult with doctor for recommendations.

For External use only.

Do not use:on wounds, raw surfaces or blistered areas, with a heating pad, or if allergic to product ingredients

When using this product: Avoid eye contact; do not use excessive amounts; do not exceed recommended dosage unless directed by doctor; do not bandage applied area.

Stop and ask doctor if:an allergic reaction occurs; condition worsens or does not improve within 7 days.

If pregnant or breast-feeding:consult with doctor before use.

if swallowed, get medical help or contact a Poison Control Center.

Precautions Concerning Children

Keep out of reach of children.

Other Information:

Store at 20 ^{o}- 25 ^{o}C (68 ^{o}- 77 ^{o}F),. Protect from freezing or storing in direct sunlight.

*Arnica Montana*flower extract, cetearyl alcohol, cetyl ester waxes, cyclopentasiloxane, disodium EDTA, ethoxydiglycol, fragrance, *Helianthus annuus*(sunflower) oil, *Lavandula*

Angustifolio(lavender) oil, methylparaben, PEG40 hydrogenated caster oil, poly(acrylic acid) 2-propionic acid homopolymer, propylene glycol, propylparaben, tetrahydrocurcumin, tocopherol acetate, triethanolamine, water.

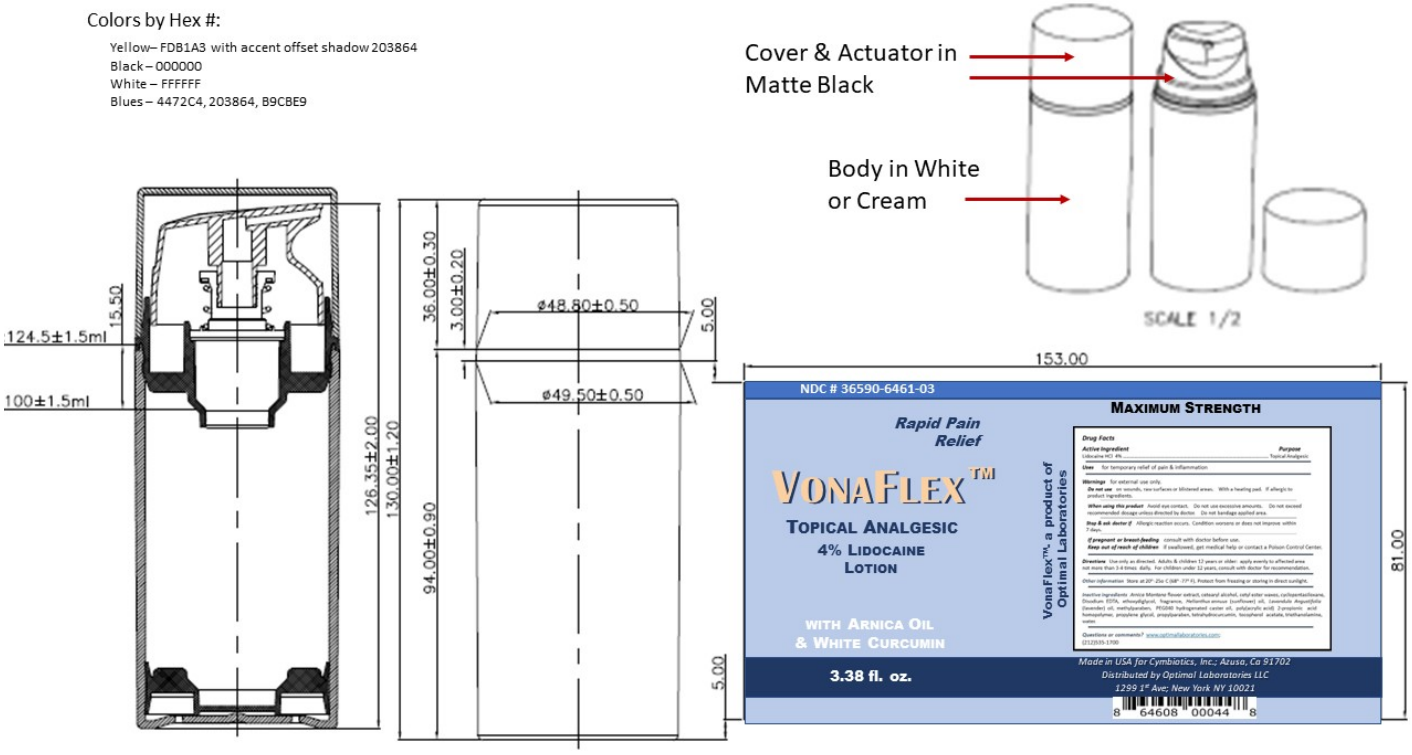
Questions and Comments

www.optimallabortories.com

(212) 535-1700

Package Label and Principal Display Panel Vonaflex

NDC 36590-6451-03 front & back label



VONAFLEX

lidocaine lotion lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36590-6461
Route of Administration	TOPICAL, CUTANEOUS, VAGINAL, RECTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	0.2 g in 100 g
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.1 g in 100 g
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.02 g in 100 g
WATER (UNII: 059QF0KO0R)	71.93 g in 100 g
SUNFLOWER OIL (UNII: 3W1JG795YI)	0.75 g in 100 g
CARBOMER 940 (UNII: 4Q93RCW27E)	0.55 g in 100 g
LAVENDER OIL (UNII: ZBP1YXW0H8)	1 g in 100 g
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	1 g in 100 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	4 g in 100 g
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	5 g in 100 g
CETYL ESTERS WAX (UNII: D072FFP9GU)	4 g in 100 g
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	2 g in 100 g
TETRAHYDRODIFERULOYLMETHANE (UNII: 00U0645U03)	2 g in 100 g
TROLAMINE (UNII: 9O3K93S3TK)	1.5 g in 100 g
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	1.2 g in 100 g
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	0.4 g in 100 g
FRAGRANCE LAVENDER ROSE ORC1004596 (UNII: 1XW43TV4PI)	0.1 g in 100 g
ARNICA MONTANA FLOWER WATER (UNII: U7L2JP51PR)	0.25 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36590-6461-1	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/25/2023	
2	NDC:36590-6461-2	75 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/25/2023	
3	NDC:36590-6461-3	100 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/26/2022	
4	NDC:36590-6461-4	150 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/26/2022	
5	NDC:36590-6461-5	200 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/25/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/25/2022	

Labeler - Cymbiotics, Inc (781766709)

Registrant - Westwood Laboratories, LLC (832280635)

Establishment

Name	Address	ID/FEI	Business Operations
Westwood Laboratories, LLC		832280635	manufacture(36590-6461) , label(36590-6461) , pack(36590-6461)

Revised: 11/2023

Cymbiotics, Inc