



YOWCH FOR MINOR BURNS BY PAIN BALM- lidocaine hcl cream
Ridge Properties

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

FDA Registered NDC# 69804-004-02	Uses - For temporary relief of pain & itching from minor burns	Directions - Test skin to sensitivity prior to use. Apply generously to affected area as needed for relief of pain and itching. Discontinue use if sensitivity occurs. Do not use on face	<p style="text-align: center;">YOWCH!!! <i>For Minor Burns</i></p> <p style="text-align: center;">2 OZ Balm by  Natural Burn Relief</p> <p style="text-align: center;">WITH ADDED LIDOCAINE</p>	Stop use and ask a doctor if - Skin becomes irritated - Condition worsens or symptoms last longer than 7 days - Symptoms clear up then reoccur within a few days	Other information: This product was manufactured by Pain Relief Naturally. For contact info please visit www.PAINBALM.net	Warning - Keep out of reach of children - For external use only - Avoid contact with the eyes	 6 38353 87216 8
Drug Facts: For professional use only	Do Not Use if you have any known allergy to any of the ingredients in this product. Discontinue use and seek medical attention should any occur	Inactive Ingredients Witch Hazel, Organic Alcohol, (BTMS 50 - A Naturally Derived extract of the Colza Seed), Cocobutter, Propolis, Oils of Coconut, Aloe Vera, Mango Kern, Eucalyptus, Walnut, Almond, Moringa, Rosehip, nutmeg					
Active ingredients: Lidocaine HCL 2% Purpose: Topical Anesthetic							

Directions - Test skin to sensitivity prior to use. Apply generously to affected area as needed for relief of pain and itching. Discontinue use if sensitivity occurs. Do not use on face

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Inactive Ingredients

Witch Hazel, Organic Alcohol, (BTMS 50 - A Naturally Derived extract of the Colza Seed), Cocobutter, Propolis, Oils of Coconut, Aloe Vera, Mango Kern, Eucalyptus, Walnut, Almond, Moringa, Rosehip, nutmeg

Purpose:

Topical Anesthetic

Warning - Keep out of reach of children - For external use only - Avoid contact with the eyes

Uses - For temporary relief of pain & itching from minor burns

Active ingredients:
Lidocaine HCL

2%

YOWCH FOR MINOR BURNS BY PAIN BALM

lidocaine hcl cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69804-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1000 mg

Inactive Ingredients

Ingredient Name	Strength
COCOA BUTTER (UNII: 512OYT1CRR)	25 mg in 1000 mg
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	25 mg in 1000 mg
NUTMEG OIL (UNII: Z1CLM48948)	5 mg in 1000 mg
BEHENTRIMONIUM METHO SULFATE (UNII: 5SHP745C61)	60 mg in 1000 mg
MANGO SEED OIL (UNII: K8LOR30915)	45 mg in 1000 mg
WITCH HAZEL (UNII: 10114J0U34)	600 mg in 1000 mg

WALNUT OIL (UNII: Y0P3555R51)	25 mg in 1000 mg
ALOE VERA LEAF (UNII: ZY81Z83H0X)	70 mg in 1000 mg
EUCALYPTUS OIL (UNII: 2R04ONI662)	25 mg in 1000 mg
MORINGA OLEIFERA SEED OIL (UNII: REM6A5QMC0)	25 mg in 1000 mg
ALMOND OIL (UNII: 66YXD4DKO9)	25 mg in 1000 mg
ROSA CANINA FLOWER OIL (UNII: DUY7M48IIT)	25 mg in 1000 mg
COCONUT OIL (UNII: Q9L0O73W7L)	25 mg in 1000 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69804-004-02	57600 mg in 1 JAR; Type 0: Not a Combination Product		
2	NDC:69804-004-03	113400 mg in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/07/2015	

Labeler - Ridge Properties (029478762)

Establishment

Name	Address	ID/FEI	Business Operations
Ridge Properties		029478762	manufacture(69804-004)

Revised: 9/2015

Ridge Properties