

YOWCH EXTRA STRENGTH FOR MINOR BURNS- 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.

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

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

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

Purpose:

Topical Anesthetic

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

Active ingredients:

Lidocaine HCL 4%

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

FDA Registered NDC# 69804-006-02	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		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
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	Active ingredients: Lidocaine HCL 4% Purpose: Topical Anesthetic		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		

YOWCH EXTRA STRENGTH FOR MINOR BURNS

lidocaine hcl cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69804-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	40 mg in 1000 mg

Inactive Ingredients

Ingredient Name	Strength
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	60 mg in 1000 mg
MANGO SEED OIL (UNII: K8LOR30915)	35 mg in 1000 mg
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	15 mg in 1000 mg
COCONUT OIL (UNII: Q9L0O73W7L)	25 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
NUTMEG OIL (UNII: Z1CLM48948)	5 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
COCOA BUTTER (UNII: 512OYT1CRR)	25 mg in 1000 mg
WITCH HAZEL (UNII: 101I4J0U34)	600 mg in 1000 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69804-006-02	56700 mg in 1 JAR; Type 0: Not a Combination Product	11/30/2015	
2	NDC:69804-006-03	113400 mg in 1 JAR; Type 0: Not a Combination Product	11/30/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/30/2015	

Labeler - Ridge Properties (029478762)

Establishment

Name	Address	ID/FEI	Business Operations
Ridge Properties		029478762	manufacture(69804-006)

Revised: 11/2015

Ridge Properties