BURN RELIEF- allantoin, lidocaine, menthol cream
HUMN Pharmaceuticals Inc

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.

Burn Relief Cream

Active ingredients

Allantoin 1.5% (w/w)

Lidocaine Hydrochloride 4.0% (w/w)

Menthol 1.0% (w/w)

Purpose

Skin protectant

Anesthetic

Analgesic, anesthetic, and antipruritic

Uses

Temporary relief of pain associated with:

▪ minor burns ▪ minor skin irritations

Temporary protection of minor skin irritations

Warnings

For external use only.

Do not use

in large quantities, particularly:

• over raw surfaces • over blistered areas

Ask a doctor before use

if child is under 2 years of age, and use only as directed

When using this product

• avoid contact with eyes; if this happens, rinse thoroughly with water

Stop use and ask a doctor

• condition worsens • if symptoms persist for more than 7 days

• clear up and occur again within a few days • you experience: pain, swelling, or blistering

• you experience: weakness, confusion, headache, difficulty breathing, or any unusual symptoms

• you experience: pale, grey or blue-coloured skin, lips, or nail beds

Keep out of reach of children. If swallowed, get

medical help or contact a Poison Control Center right away.

Directions

• adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.

Other information

• do not use if seal is broken

• store at 60-85° F

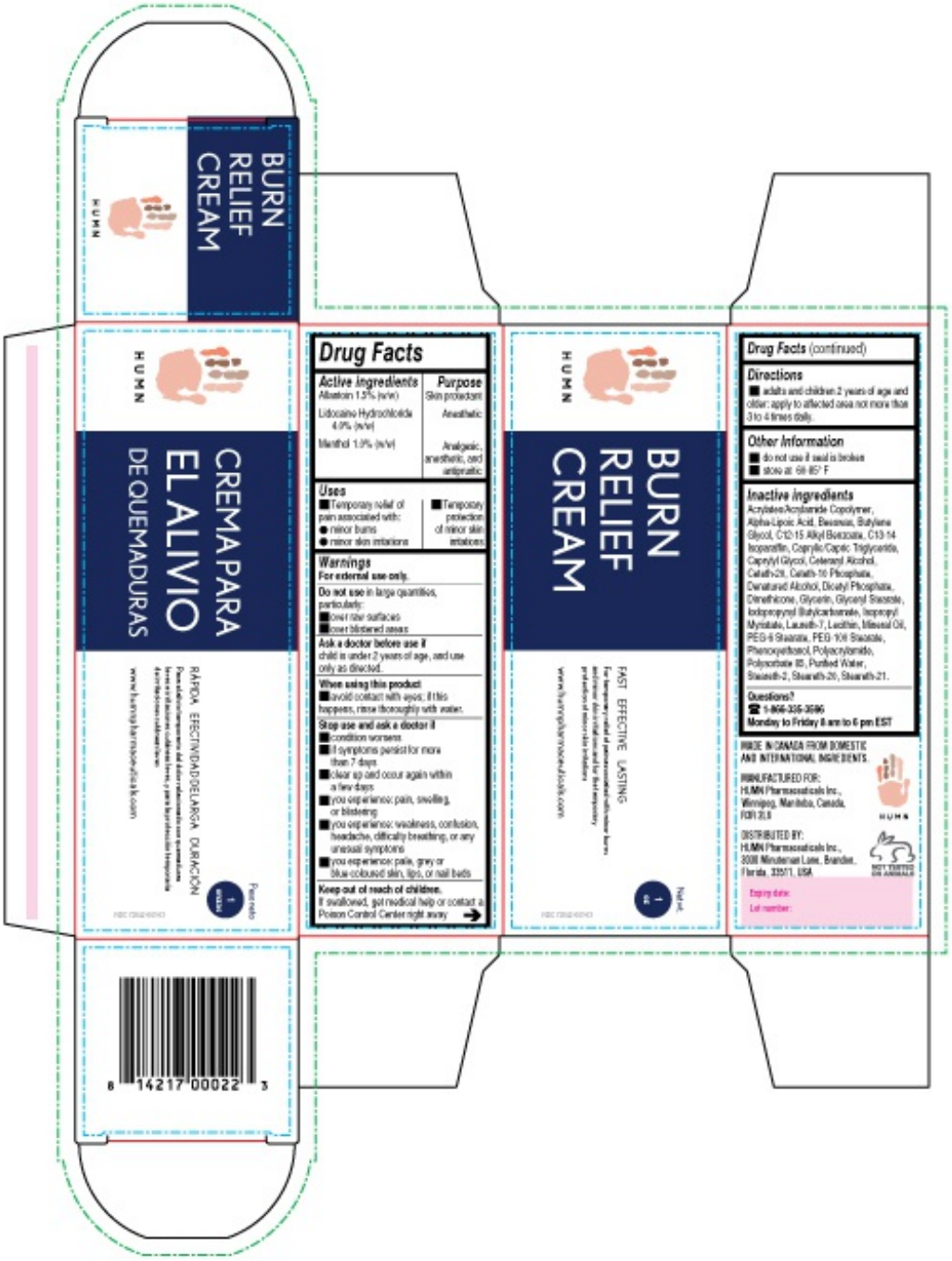
Inactive ingredients

Acrylates/Acrylamide Copolymer, Alpha-Lipoic Acid, Beeswax, Butylene Glycol, C12-15 Alkyl Benzoate, C13-14 Isoparaffin, Caprylic/Capric Triglyceride, Caprylyl Glycol, Ceteraryl Alcohol, Ceteth-20, Ceteth-10 Phosphate, Denatured Alcohol, Dicetyl Phosphate, Dimethicone, Glycerin, Glyceryl Stearate, Iodopropynyl Butylcarbamate, Isopropyl Myristate, Laureth-7, Lecithin, Mineral Oil, PEG-6 Stearate, PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Polysorbate 85, Purified Water, Steareth-2, Steareth-20, Steareth-21.

Questions?

1-866-335-3596 Monday to Friday 8 am to 6 pm EST .

Burn Relief Label.jpg



BURN RELIEF

allantoin, lidocaine, menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72042-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 mg in 100 mg
LIDOCAINE HYDROCHLORIDE ANHYDROUS (UNII: EC2CNF7XFP) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 mg in 100 mg
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	1.5 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
CETETH-20 (UNII: I835H2IHHX)	
ALCOHOL (UNII: 3K9958V90M)	
ALUMINUM DICETYL PHOSPHATE (UNII: WMV3R5DS7O)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEG-6 STEARATE (UNII: 8LQC57C6B0)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-20 (UNII: L0Q8IK9E08)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
PEG-120 GLYCERYL STEARATE (UNII: 6941286E4I)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LAURETH-7 (UNII: Z95S6G8201)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIMETHICONE 100 (UNII: RO266O364U)	
POLYSORBATE 85 (UNII: A7F3N56197)	
WATER (UNII: 059QF0KO0R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
ACRYLAMIDE (UNII: 20R035KLCI)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
.ALPHA.-LIPOIC ACID (UNII: 73Y7P0K73Y)	
STEARETH-21 (UNII: 53J3F32P58)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72042-003-03	1 in 1 CARTON	05/19/2018	
1		28300 mg in 1 TUBE; 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	05/16/2018	

Labeler - HUMN Pharmaceuticals Inc (245630272)

Registrant - Delta Pharma Inc (200161730)

Establishment

Name	Address	ID/FEI	Business Operations
Delta Pharma Inc.		200161730	manufacture(72042-003)

Revised: 5/2018 HUMN Pharmaceuticals Inc