PERFORMANCE BRANDS STEEL RELEAF PAIN RELIEVING LIQUID- lidocaine hydrochloride, menthol liquid
Prime Enterprises, 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.

Steel Releaf Pain Relieving Liquid

Active Ingredients

Lidocaine Hydrochloride 4%

Menthol 1%

Purpose

Topical Analgesic

Uses

For temporary relief of pain

Warnings

For external use only

Do not use
- More than one recommended dose at a time
- On broken or irritated skin
- If you are allergic to any ingredients of this product
- In large quantities, particularly over raw surfaces or blistered areas

When using this product
- Use only as directed
- Avoid contact with eyes
- Do not wrap the treated skin with plastic wrap or other dressings or apply heat to the skin

Stop use and ask a doctor if
- Condition worsens or symptoms persist for more than 7 days or clear up and occurs again
- Skin reactions occur, such as rash, itching, redness or irritation

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years and over

- Clean and dry affected area
- Apply once, not to exceed 3 to 4 times daily
- Roll on affected area of skin
- Children under 12 years of age: Consult a doctor

Other Information

Store at 20-25°C (68-77°F)

- Avoid storing product in direct sunlight
- Protect product from excessive moistre
- You may report serious side effects to (800) 555-8895

Inactive ingredients

Acrylamide/Sodium Acrylate Copolymer, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Arnica Montana Flower Extract, Borago Officinalis Seed Oil, Boswellia Serrata Extract, Camellia Oleifera (Green Tea) Leaf Extract, Hemp Derived Isolate (HDI), Chamomilla Recutita (Matricaria) Flower Extract, Curcuma Longa (Turmeric) Root Extract, Glycerin, Harpagophytum Procumbens (Devil's Claw) Root Extract, Mentha Piperita (Peppermint) Oil, Mineral Oil, Oenothera Biennis (Evening Primrose) Oil, Polysorbate 20, Propylene Glycol, Ribes Nigrum (Black Currant) Fruit Extract, Salix Alba (White Willow) Bark Extract, SD Alcohol 40-B, Sodium Hydroxide, Trideceth-6, Water (Aqua)

Steel Releaf® Hemp-Derived Muscle and Joint Formula Pain Relieveing Liquid with Lidocaine and Menthol

PERFORMANCE BRANDS STEEL RELEAF PAIN RELIEVING LIQUID

lidocaine hydrochloride, menthol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0268
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	9.5 mg in 1 mL
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	38 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
WATER (UNII: 059QF0KO0R)	
CANNABIDIOL (UNII: 19GBJ60SN5)	

HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 1OYM338E89)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
BLACK CURRANT (UNII: 9755T40D11)	
ALCOHOL (UNII: 3K9958V90M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BORAGE SEED OIL (UNII: F8XAG1755S)	
GLYCERIN (UNII: PDC6A3C0OX)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
TURMERIC (UNII: 856YO1Z64F)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
CHAMOMILE (UNII: FGL3685T2X)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
MINERAL OIL (UNII: T5L8T28FGP)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	

Product Characteristics

Color	white (White to off-White)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0268-3	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2019	10/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/02/2019	10/31/2024

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises			label(58443-0268) , pack(58443-0268) , manufacture(58443-0268)

Prime Enterprises, Inc.		101946028	label(58443-0268) , pack(58443-0268) , manufacture(58443-0268) , analysis(58443-0268)