

ETERNAL SPIRIT BEAUTY PAINLESS PAIN RELIEVING CREAM- menthol cream
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.

Eternal Spirit Beauty Painless Pain Relieving Cream

Active Ingredients

Menthol 1.25%

Purpose

Topical Analgesic

Indications:

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains. Provides penetrating pain relief.

For external use only.

- Avoid contact with the eyes

If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

Do not apply to wounds or damaged skin. Do not bandage tightly.

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 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a doctor.

Water (Aqua), Helianthus Annuus (Sunflower) Seed Oil, Propylene Glycol, Glycerin, Glyceryl Stearate, Acrylamide Sodium Acrylate Copolymer, Arnica Montana Flower Extract, Cetyl Alcohol, PEG-100 Stearate, Mineral Oil, Ethoxydiglycol, Boswellia Serrata Extract, Dimethicone, Butyrospermum Parkii (Shea Butter), Fragrance (Parfum), Diazolidinyl Urea, Methylparaben, Trideceth-6, Disodium EDTA, Propylparaben, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Tocopheryl Acetate, Glycyrrhiza Glabra (Licorice) Root Extract, Dimethyl Sulfone, Choline Bitartrate, Pyridoxine, Glucosamine Sulfate, Camphor, Cetyl Myristoleate, Triethanolamine

Questions or Comments?

Worldwide Cosmetics, Inc.

Eternal Spirit Beauty Painless Pain Relieving Cream

Drug Facts

Active Ingredients	Purpose
Menthol 1.25%	Tropical Analgesic

Indications: For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains. Provides penetrating pain relief.

Warning: For external use only. Avoid contact with the eyes. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor. Do not apply to wounds or damaged skin. Do not bandage tightly. 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 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a doctor.



PAINLESS

Pain relieving cream

Penetrating pain relief.

Ultimate Treatment to relieve common pain. Arthritis - carpal tunnel syndrome - tennis & golfer's lateral elbow pain.

4FL.Oz./118mL

Inactive Ingredients: Water (Aqua), Helianthus Annuus (Sunflower) Seed Oil, Propylene Glycol, Glycerin, Glyceryl Stearate, Acrylamide Sodium Acrylate Copolymer, Arnica Montana Flower Extract, Cetyl Alcohol, PEG-100 Stearate, Mineral Oil, Ethoxydiglycol, Boswellia Serrata Extract, Dimethicone, Butyrospermum Parkii (Shea Butter), Fragrance (Parfum), Diazolidinyl Urea, Methylparaben, Trideceth-6, Disodium EDTA, Propylparaben, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Tocopheryl Acetate, Glycyrrhiza Glabra (Licorice) Root Extract, Dimethyl Sulfone, Choline Bitartrate, Pyridoxine, Glucosamine Sulfate, Camphor, Cetyl Myristoleate, Triethanolamine.

Questions or Comments
Worldwide Cosmetics, Inc.

Distributed by: Worldwide Cosmetics, Inc.
12105 S.W. 130th Street, Suite 204
Miami, FL 33186 / Made in USA
www.eternalspiritbeauty.com

3.81

ETERNAL SPIRIT BEAUTY PAINLESS PAIN RELIEVING CREAM

menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 443-0223
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	12.13 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)			
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)			
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)			
SHEA BUTTER (UNII: K49155WL9Y)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
TEA TREE OIL (UNII: VIF565UC2G)			
CHOLINE BITARTRATE (UNII: 6K2W7T9V6Y)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
MINERAL OIL (UNII: T5L8T28FGP)			
PYRIDOXINE (UNII: KV2JZ1BI6Z)			
TROLAMINE (UNII: 9O3K93S3TK)			
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)			

CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LICORICE (UNII: 61ZBX54883)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CETYL MYRISTOLEATE (UNII: 87P8K33Q5X)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0223-3	118 mL in 1 JAR; Type 0: Not a Combination Product	01/29/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	01/29/2016	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0223) , manufacture(58443-0223) , label(58443-0223) , analysis(58443-0223)