DIRT PAIN RELIEVING GEL- menthol gel
PURIVITAE, LLC

DIRT Pain Relieving Gel

Drug Facts

Active Ingredients:

Menthol 4%

Purpose

Topical Analgesic

Uses:

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

Warnings:

For external use only

Do not use

- on damaged or broken skin

When using this product

- avoid contact with the eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

If pregnant or breast-feeding,

ask a health professional before use

Directions:

Adults and children over 12 years of age:

ask a doctor **Children 12 years or younger:**

- apply generously to affected areas
- rub into affected area until absorbed into the skin
- repeat as necessary, but no more than 4 times daily

Inactive Ingredients:

Activated Charcoal, Acrylates/Cl0-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Amica Montana Flower Extract, Boswellia Serrata Extract, Calendula Officinalis Extract, Ethylhexylglycerin, Eucalyptus Globulus Oil, Glycerin, llex Paraguariensis (Verba Mate') Extract, Melaleuca Alternilolia (Tea Tree) Oil, Methylsulfonylmethane (MSM), Phenoxyethanol, Polysorbate-20, Propylene Glycol, SD-Alcohol 40B, Tocopheryl Acetate (Vitamin E), Triethanolamine.

Package Labeliing:

DIRT PAIN RELIEVING GEL
menthol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83067-463
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83067-463-00	88 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/03/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	10/03/2023	

Labeler - PURIVITAE, LLC (086896991)