ONEBACK- menthol gel WORLD WIDE MEDICAL SERVICES, 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.

ACTIVE INGREDIENTS

NATURAL MENTHOL 3.9%

PURPOSE

COOLING PAIN RELIEF

USES

TEMPORARY RELIEF OF

- ARTHRITIS
- BACKACHE
- STRAINS
- SPRAINS

WARNINGS

FOR EXTERNAL USE ONLY

DO NOT USE NEAR EYES, MOUTH, MUCUS MEMBRANES, CUTS, RASHES, AND SORES. IF CONTACT OCCURS, FLUSH WITH COLD WATER.

DO NOT USE WITH HEATING PAD OR DEVICE, OR UNDER BANDAGE.

DO NOT USE IF PREGNANT OR BREAST FEEDING. PLEASE CONSULT YOUR PHYSICIAN PRIOR TO USE.

DO NOT APPLY TO WOUNDS OR DAMAGED SKIN.

STOP USE AND ASK A DOCTOR IF IRRITATION PERSISTS.

KEEP OUT OF REACH OF CHILDREN. IF ACCIDENTALLY INGESTED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

- ADULTS AND CHILDREN 2 YEARS OF AGE AND OLDER: APPLY TO AFFECTED AREA NOT MORE THAN 3 TO 4 TIMES DAILY
- RUB IN THOROUGHLY UNTIL IT IS ABSORBED.

INACTIVE INGREDIENTS

WATER, ISOPROPYL ALCOHOL, PROPYLENE GLYCOL, GLYCERINE, CARBOMER, ILEX PARAGUARIENSIS LEAF EXTRACT, HYDRATED SILICA, AMINOMETHYL PROPANOL, METHYL PARABEN, UNCARIA TOMENTOSA EXTRACT, BOSWEILA SERRATA EXTRACT, CAMPHOR FOR SCENT



3.9% Natural Menthol Ilex Boswelia Uncaria Tomentosa

OneBack™ with Cat's Claw Topical Cool Pain Relieving Gel provides fast, long-lasting relief from minor pains and aches associated with accident victims, strenuous exercise, daily activities and the stresses of life. Cat's Claw is regulated by the FDA over the counter pharmaceutical guidelines and is sold exclusively through Healthcare Practitioners.

3 FL. OZ. (88.8ML.) NDC#61461-107-03

Cool Pain Relieving Gel

Drug Facts

Active ingredients

Purpose Natural Menthol 3.9%Cooling Pain Reliever

Uses temporary relief of

■arthritis ■backache ■strains ■sprains

Warnings

For external use only

Do not use near eyes, mouth, mucus membranes, cuts, rashes, and sores. If contact occurs, flush with cold water.

Do not use with heating pad or device, or under bandage.

Do not use if pregnant or breast feeding. Please consult your Physician prior to use.

Do not apply to wounds or damaged skin.

Stop use and ask a doctor if irritation persists.

Keep out of reach of children. If accidentally ingested, get medical help or contact a Poison Control Center immediately.

Directions ■adults and children 2 years of age and older: apply to affected area not more that 3 to 4 times daily **ur**ub in thoroughly until gel is absorbed.

Inactive ingredients Water, Isopropyl Alcohol, Propylene Glycol, Glycerine, Carbomer, Ilex Paraguariensis Leaf Extract, Hydrated Silica, Aminomethyl Propanol, Methyl Paraben, Uncaria Tomentosa Extract, Boswelia Serrata Extract, Camphor for Scent



800-918-0827 www.onebackworks.com Made in the USA

ONEBACK

menthol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69643-101

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A) MENTHOL 3.9 g in 100 mL

Inactive Ingredients

Ingredient Name Strength WATER (UNII: 059QF0KO0R) ISOPROPYL ALCOHOL (UNII: ND2M416302) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) GLYCERIN (UNII: PDC6A3C0OX) CARBOMER 940 (UNII: 4Q93RCW27E) ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F) **HYDRATED SILICA** (UNII: Y6O7T4G8P9)

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
METHYLPARABEN (UNII: A218 C7HI9T)	
UNCARIA TOMENTOSA LEAF (UNII: 487U8M3D2P)	
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)	
CAMPHOR OIL (UNII: 75IZZ8 Y727)	

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:69643-101-11	88.8 mL in 1 BOTTLE; 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	03/03/2015		

Labeler - WORLD WIDE MEDICAL SERVICES, INC. (101816366)

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