ONE GEL SPORT PAIN RELIEVING- camphor (synthetic) and menthol gel Phyto Creativ

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.

One Gel Sport Pain relieving gel

Phyto Creativ Drug Facts

Active Ingredients	Purpose
Camphor 3%	Pain Reliever
Menthol 2.2%	Pain Reliever

Uses

For the temporary relief of minor aches and pains of muscles and joints

Warnings

For external use only

Do not use on wounds, damaged skin or irritated areas a heating pad on treated area

When using this product use only as directed avoid contact with eyes and mucous membranes do not bandage tightly

Stop use and ask doctor if condition worsens, or if symptoms persist for more than 7 days conditions clear up and occur again within a few days.

If pregnant or breast-feeding ask a healthcare professional before use.

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

Directions

Adults and Children 7 years of age and older: apply to the affected area up to 3 times daily, as needed.

Inactive Ingredients

Alcohol, carbomer, equisetum arvense extract, FD&C Blue No. 1, limonene, linalool, malaleuca leucadendron cajaput oil, potassium sorbate, PPG-1-PEG-9 lauryl glycol esther, rosmarinus officinals malaleuca, sodium benzoate, sodium hydroxide, thymus vulgaris, water.

Distributed by One Gel USA Inc. Lighthouse Point, FL 33064

PRINCIPAL DISPLAY PANEL - 100 ml Bottle Label

one gel Sport

TWIST CAP TO OPEN

Laboratoires

Phyto Creativ

USA

Paraben free Phenoxyethanol free Essential oils

 $\prod TM$

one gel *Sport*

Pain Relieving Gel

NET WT: 3.38 oz. (100 ml)



ONE GEL SPORT PAIN RELIEVING camphor (synthetic) and menthol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:69023-100

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Camphor (Synthetic) (UNII: 5TJD82A1ET) (Camphor (Synthetic) - UNII:5TJD82A1ET)	Camphor (Synthetic)	30 mg in 1 mL	
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	22 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
Alcohol (UNII: 3K9958V90M)		
equisetum arvense branch (UNII: 1L0 VKZ185E)		
fd&c blue no. 1 (UNII: H3R47K3TBD)		
linalool, (+/-)- (UNII: D81QY6I88E)		
potassium sorbate (UNII: 1VPU26JZZ4)		
sodium benzoate (UNII: OJ245FE5EU)		
sodium hydroxide (UNII: 55X04QC32I)		
water (UNII: 059QF0KO0R)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69023-100-30	100 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	07/04/2014	

Labeler - Phyto Creativ (263842260)

Establishment			
Name	Address	ID/FEI	Business Operations
Phyto Creativ		263842260	MANUFACTURE(69023-100)

Revised: 8/2014 Phyto Creativ