REAL TIME PAIN RELIEF MAXX TOPICAL ANALGESIC- menthol 1.5% lotion
Cosmetic Specialty Labs, 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.

Real Time Pain Relief George Foreman Knockout Formula

Drug Facts

Active Ingredient

Menthol 1.5%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with:

- arthritis
- simple backache
- muscle strains
- sprains
- bruises
- cramps

Warnings

for external use only

When using this product

- use only as directed
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- irritation develops

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

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

Directions

adults and children over 2 years:

- apply generously to affected area

- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 4 times daily

children 2 years or younger: ask a doctor

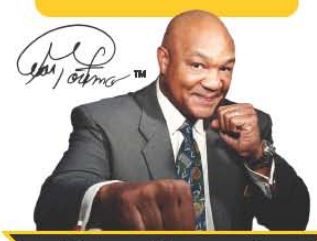
Inactive ingredients

Aloe Barbadensis Leaf, Anthemis nobilis, Arnica Montana Flower Extract, Butylene Glycol, Calendula officianlis, Caprylyl Glycol, Capsicum Frutescens Fruit, Carbomer, Centaurea cyanus, Cetearyl Alcohol, Cetyl Alcohol, Coriandrum Sativum (Coriander) Fruit Oil, Diazolidinyl Urea, Emu Oil, Glucosamine HCI, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Hypericum perforatum, Matricaria chamomilla, Mentha Piperita (Peppermint) Leaf Oil, Methylsulfonylmethane, Phenoxyethanol, Purified Water, Salix Alba (Willow) Bark Extract, SD Alcohol 40, Sodium Chondroitin Sulfate, Sorbitol, Tilia cordata, Triethanolamine.

Distributed by: RTPR LLC, Edmond, OK 73012

PRINCIPAL DISPLAY PANEL - 120 mL Label

REAL TIME Pain Relief®



George Foreman's

KNOCKOUT FORMULA®

Provides Temporary Relief from:
Arthritis, Simple Backache, Muscle Strains, Sprains, Bruises, Cramps.

Topical Analgesic Lotion

Net Wt. 4 Fl. Oz. / 120 mL

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Inactive Ingredients: Aloe Barbadensis Leaf Juice, Anthemis nobilis (Roman Chamomile) Flower Extract, Arnica montana Flower Extract, Butylene Glycol, Calendula officinalis (Marigold), Caprylyl Glycol, Carbomer, Centaurea cyanus (Cornflower), Cetearyl Alcohol, Cetyl Alcohol, Chamomilla recutita (Matricaria Chamomilla), Coleonema album (Confander) Fruit Oil, Cupressus sempervirens (Cypress) Fruit Extract, Curcuma longa (Turmeric) Root Extract, Emu Oil, Fragrance, Gaultheria procumbens (Wintergreen) Oil, Glycerin, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Helichrysum italicum Flower, Hypericum perforatum (St. John's Wort), Jasminum officinale (Jasmine) Flower Extract, Lavandula angustifolia (Lavender) Oil, Magnesium Oxide, Methylsulfonylmethane, Myristica fragrans (Nutmeg) Extract, Origanum Majorana (Marjoram) Leaf Extract, Phenoxyethanol, Purified Water, Rosmarinus officinalis (Rosemary) Leaf Extract, Salix alba (Willow) Bark Extract, SD Alcohol 40, Sorbitol, Tilia cordata (Lime Tree), Triethanolamine.

NDC #58133-100-60
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REAL TIME PAIN RELIEF MAXX TOPICAL ANALGESIC

menthol 1.5% lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58133-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.5 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
HYPERICUM PERFORATUM FLOWER (UNII: A6V4CUE7PV)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHANOLAMINE TRIS(DIHYDROGEN PHOSPHATE) (UNII: 36YHT392ID)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CAPSICUM (UNII: 00UK7646FG)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
CENTAUREA CYANUS FLOWER (UNII: QZ239038YC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CORIANDER OIL (UNII: 7626GC95E5)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EMU OIL (UNII: 344821WD61)	
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A)	
SORBITOL (UNII: 506T60A25R)	
TILIA X EUROPAEA FLOWER (UNII: NHV2K1OUDH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
ANTHEMIS ARVENSIS FLOWERING TOP (UNII: 851IP1R9YK)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58133-100-	97.5 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2015	

1	33	97.5 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2015	
2	NDC:58133-100-04	120 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2014	
3	NDC:58133-100-15	45 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2014	
4	NDC:58133-100-12	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/01/2014	
5	NDC:58133-100-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/01/2014	
6	NDC:58133-100-60	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/10/2020	
7	NDC:58133-100-62	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2014	

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Registrant - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-100)

Revised: 2/2020 Cosmetic Specialty Labs, Inc.