BUFFERIN PAIN RELIEF- menthol, camphor, and methyl salicylate cream Genomma Lab USA

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.

Bufferin® Pain Relief Cream

Drug Facts

Active ingredients

Camphor 4%, Menthol 10% Methyl salicylate 30%

Purpose

Topical analgesics

Uses

Temporarily relieves the minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

Allergy alert

• If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have redness over the affected area.

When using this product

- use only as directed
- avoid contact with eyes or mucous membranes or rashes
- do not bandage tightly

Stop use and ask a doctor If

- redness is present or irritation or rash develops
- conditions worsen or symptoms clear up and occur again within a few days

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 immediately.

Directions

use only as directed

Adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily

Chidren under 12 years of age: ask a doctor

Other information

- store at 15 to 30"C (59 to 86"F)
- Tamper Evident: DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

Inactive ingredients

Purified water, Glycerin, Glycerol monostearate (GMS), Stearyl alcohol, Cetyl alcohol, Hemp seed oil, Stearic acid, Isopropyl palmitate, Polyacrylic acid, Potassium cetyl phosphate, Triethanolamine (TEA), Methylparaben, Propylparaben

Questions or comments?

Call toll free 1-877-994-3666

DISTRIBUTED BY: GENOMMA LAB USA, INC., HOUSTON, TX 77098

PRINCIPAL DISPLAY PANEL - 56.7 g Tube Carton

irwin naturals®

BUFFERIN® + 1000 mg Hemp Seed Oil* PER TUBE CURATED FROM IRWIN NATURALS®

PAIN RELIEF CREAM ULTRA STRENGTH

FAST ACTING
DEEP PENETRATING
*FOR SKIN CONDITIONING

FAST RELIEF OF MUSCLE, BACK AND JOINT PAIN

NET. WT 2.0 OZ (56.7 g)









PAIN RELIEF CREAM
ULTRA STRENGTH

FAST ACTING
DEEP PENETRATING
*FOR SKIN CONDITIONING

FAST RELIEF OF MUSCLE,







BUFFERIN PAIN RELIEF

menthol, camphor, and methyl salicylate cream

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50066-615

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL, (+)- (UNII: C6B1OE8P3W) (MENTHOL, (+) UNII:C6B1OE8P3W)	MENTHOL, (+)-	100 mg in 1 g	
CAMPHOR, (-)- (UNII: 213N3S8275) (CAMPHOR, (-) UNII:213N3S8275)	CAMPHOR, (-)-	40 mg in 1 g	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ 4LPZ)	METHYL SALICYLATE	300 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
Water (UNII: 059QF0KO0R)	
glycerin (UNII: PDC6A3C0OX)	
Stearyl alcohol (UNII: 2KR89I4H1Y)	
cetyl alcohol (UNII: 936JST6JCN)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:50066-615- 20	1 in 1 CARTON	08/18/2023			
1		56.7 g in 1 TUBE; 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	08/18/2023		

Labeler - Genomma Lab USA (832323534)

Revised: 8/2023 Genomma Lab USA