

PAIN RELIEF BALM- menthol 4% cream

Metacan Inc Ste

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.

Pain Relief Balm

Active ingredient

Menthol 4%

Purpose

Menthol 4%.....Topical Analgesic

Uses

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

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

When using this product

- avoid contact with eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask doctor if

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

If pregnant or breastfeeding, 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 12 years of age and older: Apply to affected area not more than 3 to 4 times daily.

Children under 12 years of age: consult a doctor.

Other information

- Store in a cool dry place away from light

Inactive ingredients

organic shea (burtyrospermum parkii) butter, organic carnauba (copernicia cerifera) wax, peppermint leaf oil (mentha piperita), organic sunflower (helianthus annuus) seed oil, organic jojoba (simmondsia chinensis) seed oil, organic coconut (cocos nucifera) oil, cetearyl olivate, sorbitan olivate, organic hemp (cannabis sativa) aerial part extract, organic hemp (cannabis sativa) seed oil, black pepper (piper nigrum) fruit oil (source of terpenes), clove (syzygium aromaticum) flower oil, magnesium sulfate, rosemary (rosmarinus officinalis) extract

Manufactured for HempFusion

3820 NW 14th Street Suite A & B

Topeka, KS 66618

877.NOW.HEMP (877.669.4367)

hempfusion.com

Principal Display Panel

Pain

Relief

BALM

HempFusion

Menthol 4%

Including hemp extract with naturally occurring **CBD** (50mg/jar) + **Terpenes** (45mg/jar) from black pepper and clove & other natural skin moisturizers

NON-GMO

ALL SKIN TYPES

1.4 oz (40g)

HempFusion® Sports Pain Relief Balm is a Shea butter base with penetrating Menthol for cooling relief, complemented by moisturizing Magnesium and premium Hemp extract with naturally occurring CBD + terpenes from Black Pepper and Clove.

We use the following ingredients per jar:

Hemp Extract (aerial part)	500mg (yielding 50mg CBD)
Black Pepper/Clove extract	100mg (yielding 45mg Terpenes)
Jojoba Oil	2000mg
Safflower Oil	2000mg
Shea Butter	28000mg

This product contains a total of 0.01% of only 0.01% cannabinoid concentration that does not exceed 0.3% on a dry-weight basis.

WARNING: The safety of this product has not been determined.

Drug Facts (continued)

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Drug Facts (continued)

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Manufactured for HempFusion®
3820 NW 17th Street Suite A & B
Tombola, KS 66618
97.7% CBD + 0.3% CBN (677669-4387)
hempfusion.com

Pain Relief BALM

HempFusion.

Menthol 4%

Including hemp extract with naturally occurring CBD (50mg/jar) +

Terpenes 145mg/jar from black pepper and clove & other natural skin moisturizers

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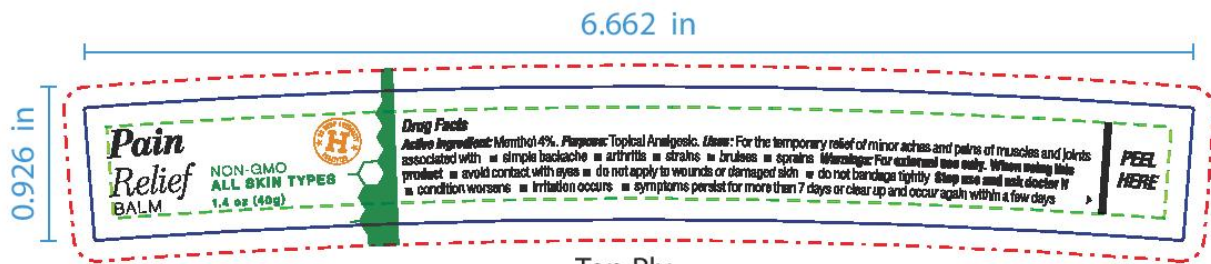
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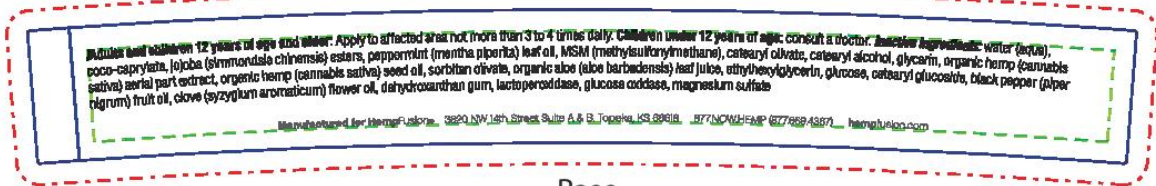
Top Ply



Back of Top Ply

NO BLEED ON BACK

EVERYTHING MUST REMAIN WITHIN GREEN TEXT LIMIT



Base



menthol 4% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73672-988
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 g

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HEMP (UNII: TD1MUT01Q7)	
BLACK PEPPER OIL (UNII: U17J84S19Z)	
SHEA BUTTER (UNII: K49155WL9Y)	
JOJOBA OIL (UNII: 724GKU717M)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
CLOVE OIL (UNII: 578389D6D0)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
ROSEMARY (UNII: IJ67X351P9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73672-988-40	1 in 1 CARTON	02/10/2020	
1		40 g in 1 CONTAINER; 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	02/10/2020	

Labeler - Metacan Inc Ste (034175227)

Establishment

Name	Address	ID/FEI	Business Operations
PakLab		078717086	manufacture(73672-988)

