

HAPPY ELF HEMP PAIN RELIEF CREAM- menthol, methyl salicylate cream

Happy Elf CBD Corporation

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.

Happy Elf Hemp Pain Relief Cream

DRUG FACTS

Menthol - 5% (External Analgesic)

Methyl Salicylate (NSAID) – 7.5% (External Analgesic)

Uses:

For temporary relief of minor aches and pains of muscles and joints associated with backache, muscle ache, strains, sprains, bruises, cramps, arthritis, and inflammation

WARNINGS:

External Use Only!

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

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.

If pregnant or breast-feeding, or if you have sensitive skin, ask your doctor before use

Avoid contact with eyes. If contact occurs, flush thoroughly with water.

When using this product:

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if: condition worsens or symptoms persist for more than 7 days, symptoms clear up and occur again within a few days, excessive skin irritation occurs

Directions:

Use only as directed. Apply generously and massage to affected area as needed. Do not use more than 3 to 4 times per day.

Children under 12 years of age: ask a doctor before use.

Inactive Ingredients:

Alpha-Tocopherol Acetate (Vitamin E), Aminomethylpropanol, Arnica Montana Flower, Hemp Oil, Carbomer, Cetostearyl Alcohol, Dimethyl Sulfone, Dimethyl Sulfoxide, Ethylhexyl Palmitate, Ethylhexylglycerin, Glucosamine, Glyceryl Monostearate, Magnesium Hydroxide, Phenoxyethanol, Polysorbate 80, Water

Other Information:

Store at room temperature 68°F to 77°F (20° to 25°C)

Do not expose to excessive heat

Allergy Alert:

Do not use if you are allergic to salicylates (including aspirin) without consulting a physician.

For Questions

Call +1 (239) 236-8158

Happy Elf CBD Corporation

2250 NW 102 PL

Miami, FL 33172

Website: www.happyelf.com.com

DRUG FACTS

Active Ingredient	Purpose
Menthol 5%	External Analgesic
Methyl Salicylate (NSAID) 7.5%	External Analgesic

Uses: For temporary relief of minor aches and pains of muscles and joints associated with backaches, muscle ache, strains, sprains, bruises, cramps, and arthritis, inflammation.

WARNINGS: For external use only!

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

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 if you have redness over the affected area.

If pregnant or breast-feeding, or if you have sensitive skin, ask your doctor before use.

Avoid contact with eyes. If contact occurs, flush thoroughly with water.

When using this product: avoid contact with eyes or mucous membranes, do not bandage tightly.

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

Directions:

Use only as directed. Apply generously and massage the affected areas as needed. Do not use more than 3 to 4 times per day.

Children under 12 years of age: ask a doctor before use.

Inactive ingredients:

Alpha-Tocopherol Acetate (Vitamin E), Aminomethylpropanol, Arnica Montana Flower, Hemp oil, Carbomer, Cetostearyl alcohol, Dimethyl Sulfone, Dimethyl Sulfoxide, Ethylhexyl Palmitate, Ethylhexylglycerin, Glucosamine, Glycerol Monostearate, Magnesium Hydroxide, Phenoxyethanol, Polysorbate 80, Water.

Other Information:

Store at room temperature 68°F to 77°F (20° to 25°C)
Do not expose to excessive heat.

Allergy Alert:

Do not use if you are allergic to salicylates (including aspirin) without consulting a physician.

For questions call: +1 (239) 236-8158
Happy Elf CBD Corporation
2250 NW 102 PL,
Miami, FL 33172
info@happyelf.com
happyelf.com
4 oz / 114 g



MADE IN USA

CHP3000



HAPPYelf

PAIN RELIEF CREAM



PREMIUM HEMP OIL

ARNICA MONTANA,
GLUCOSAMINE & MSM
NET WT 4OZ

HEMP

HAPPY elf

PAIN RELIEF CREAM

Fast Acting
Long Lasting
Pain Relief
Promotes fast muscle and joint recovery

- Full Spectrum Hemp Oil
- Doctor Formulated
- Non Psychoactive
- Made in USA
- 3rd Party Tested



PREMIUM HEMP OIL

ARNICA MONTANA,
GLUCOSAMINE & MSM
NET WT 4 OZ

DRUG FACTS

Active Ingredient	Purpose
Menthol 5%	External Analgesic
Methyl Salicylate (NSAID) 7.5%	External Analgesic

Uses: For temporary relief of minor aches and pains of muscles and joints associated with backaches, muscle ache, strains, sprains, bruises, cramps, and arthritis, inflammation.

WARNINGS: For external use only!

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Do not use on wounds or damaged skin, with a heating pad, or a child under 12 years of age with arthritis-like conditions. Ask a doctor before use if you have if you have redness over the affected area.

If pregnant or breast-feeding, or if you have sensitive skin, ask your doctor before use.

Avoid contact with eyes. If contact occurs, flush thoroughly with water.

When using this product: avoid contact with eyes or mucous membranes, do not bandage tightly.

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

Directions:

Use only as directed. Apply generously and massage the affected areas as needed. Do not use more than 3 to 4 times per day.

Children under 12 years of age: ask a doctor before use.

Inactive ingredients:

Alpha-Tocopherol Acetate (Vitamin E), Aminomethylpropanol, Arnica Montana Flower, Hemp oil, Carbomer, Cetearyl alcohol, Dimethyl Sulfone, Dimethyl Sulfoxide, Ethylhexyl Palmitate, Ethylhexylglycerin, Glucosamine, Glyceryl Monostearate, Magnesium Hydroxide, Phenoxyethanol, Polysorbate 80, Water.

Other information:

Store at room temperature 68°F to 77°F (20° to 25°C)
Do not expose to excessive heat.

Allergy Alert:

Do not use if you are allergic to salicylates (including aspirin) without consulting a physician.

For questions call: +1 (239) 236-8168
Happy Elf CBD Corporation
2259 NW 102 PL
Miami, FL 33172
info@happyelf.com
happyelf.com
4 oz / 114 g



MADE IN USA



CHP3000





DRUG FACTS

Active Ingredient	Purpose
Menthol 5%	External Analgesic
Methyl Salicylate (NSAID) 7.5%	External Analgesic

Uses: For temporary relief of minor aches and pains of muscles and joints associated with backaches, muscle ache, strains, sprains, bruises, cramps, and arthritis, inflammation.

WARNINGS: For external use only!
Keep out of reach of children.
 If swallowed, get medical help or contact a Poison Control Center immediately.

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 if you have redness over the affected area.
If pregnant or breast-feeding, or if you have sensitive skin, ask your doctor before use.
Avoid contact with eyes. If contact occurs, flush thoroughly with water.

When using this product: avoid contact with eyes or mucous membranes, do not bandage tightly.
Stop use and ask a doctor if: condition worsens or symptoms persist for more than 7 days, symptoms clear up and occur again within a few days, excessive skin irritation occurs.

Directions:
 Use only as directed. Apply generously and massage the affected areas as needed. Do not use more than 3 to 4 times per day.
 Children under 12 years of age: ask a doctor before use.

Inactive ingredients:
 Alpha-Tocopherol Acetate (Vitamin E), Aminomethylpropanol, Arnica Montana Flower, Hemp oil, Carbomer, Cetearyl alcohol, Dimethyl Sulfoxide, Dimethyl Sulfoxide, Ethylhexyl Palmitate, Ethylhexylglycerin, Glucosamine, Glycerol Monostearate, Magnesium Hydroxide, Phenoxyethanol, Polysorbate 80, Water.

Other information:
 Store at room temperature 68°F to 77°F (20° to 25°C)
 Do not expose to excessive heat.

Allergy Alert:
 Do not use if you are allergic to salicylates (including aspirin) without consulting a physician.

For questions call: +1 (239) 236-8168
 Happy Elf CBD Corporation
 2259 NW 102 PL
 Miami, FL 33172
 info@happyelf.com
 happyelf.com
 4 oz / 114 g



- Full Spectrum Hemp Oil
- Doctor Formulated
- Non Psychoactive
- Made in USA
- 3rd Party Tested



HAPPY ELF HEMP PAIN RELIEF CREAM

menthol, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73658-3401
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.05 kg in 1 kg
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.075 kg in 1 kg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
GLUCOSAMINE (UNII: N08U5BOQ1K)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
HEMP (UNII: TD1MUT01Q7)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73658-3401-1	1 in 1 CARTON	03/30/2020	
1	NDC:73658-3401-0	0.114 kg 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	03/30/2020	

Labeler - Happy Elf CBD Corporation (117409880)

Registrant - Happy Elf CBD Corporation (117409880)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc		016433141	manufacture(73658-3401) , relabel(73658-3401) , pack(73658-3401)

Revised: 4/2020

Happy Elf CBD Corporation