MEDIC ICE - menthol gel Straight Arrow Products, 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.

Active Ingredient

Menthol 7%

Purpose

Pain relieving gel

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

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

• For external use only

Do not use

- on wounds or damaged skin
- with heating pads or heating devices
- with other ointments, creams, sprays or liniments
- with tight bandages

When using this product

• avoid contact with eyes

Stop use and ask a doctor if:

- a rash appears
- condition worsens or if symptoms persist for more than 7 days, or clear up and occur again within a few days

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

Directions

- Adults and children 2 years and over: Clean skin of all other ointments, creams, sprays or liniments. Apply directly to affected areas no more than 3 to 4 times daily. Wash hands after application to help avoid contact with eyes and sensitive areas. May be used with wet or dry bandages or with ice packs.
- Children under 2 years of age: ask a doctor

Inactive Ingredients Water, Alcohol, Laureth-4, Carbomer, Triethanolamine, Aloe Vera, Benzocaine, Thymol, Camphor, Methylsulfonylmethane (MSM), Glucosamine HCl, Chondroitin Sulfate, **Oil Complex** - (Oregano, Eucalyptus, Sage, Patchouli, Lavender, Rosemary, Ginger, Peppermint),

Fragrance, **Mineral Complex** - (Magnesium Sulfate, Copper Sulfate, Calcium Sulfate, Calcium Carbonate, Lithium Chloride, Potassium Chloride, Sodium Sesquicarbonate, Ammonium Chloride), **Herbal Complex** - (Arnica, Slippery Elm, Chickweed, Comfrey, Myrrh, Hops, Marshmallow, Plantain, Green Tea), FD and C Blue No. 1.

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Descriptive Text: Medic Ice label File Name: medicice.jpg





MEDIC ICE

menthol gel

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Pro	duct	Intori	mation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:62001-0318

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.07 g in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ALCOHOL (UNII: 3K9958V90M)		
TROLAMINE (UNII: 903K93S3TK)		
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)		
BENZO CAINE (UNII: U3RS Y48 JW5)		
LAURETH-4 (UNII: 6HQ855798J)		
THYMOL (UNII: 3J50XA376E)		
ENGLISH LAVENDER OIL (UNII: ZBP1YXW0H8)		
ALOE (UNII: V5VD430 YW9)		
DIMETHYL SULFONE (UNII: 9 H4PO 4Z4FT)		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)		

MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB) ROSEMARY OIL (UNII: 8LGUTVM393) PATCHOULI OIL (UNII: F3IN55X5PO) GINGER OIL (UNII: SAS9Z1SVUK) SAGE OIL (UNII: U27K0H1H2O) OREGANO (UNII: 0E5ATBT16U) GLUCOSAMINE (UNII: NO8U5BOQ1K) CHONDRO ITIN SULFATE (BO VINE) (UNII: 6IC1M3OG5Z) LITHIUM CHLO RIDE (UNII: 6d962QA067) POTASSIUM CHLORIDE (UNII: 660 YQ981IO) CUPRIC SULFATE ANHYDROUS (UNII: KUW2Q3U1VV) AMMO NIUM CHLORIDE (UNII: 01Q9PC255D) CALCIUM SULFATE (UNII: WAT0 DDB505) CALCIUM CARBONATE (UNII: 10G9379FGK) ARNICA MONTANA (UNII: 080 TY208 ZW) ELM (UNII: 63P0E2M46Y) COMFREY (UNII: 205HXK6R3G) MYRRH (UNII: 21C71G1F3L) HOPS (UNII: 01C73H6H83) PLANTAGO MAJOR (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	PEPPERMINT OIL (UNII: AV092KU4JH)	
ROSEMARY OIL (UNII: 8LGUTVM393) PATCHOULI OIL (UNII: F3IN55X5PO) GINGER OIL (UNII: SAS9Z1SVUK) SAGE OIL (UNII: U27K0H1H2O) OREGANO (UNII: 0E5AT8T16U) GLUCOSAMINE (UNII: N08U5BOQ1K) CHONDROITIN SULFATE (BO VINE) (UNII: 6IC1M3OG5Z) LITHIUM CHLORIDE (UNII: 64962QA067) POTASSIUM CHLORIDE (UNII: 660 YQ981I0) CUPRIC SULFATE ANHYDROUS (UNII: KUW2Q3U1VV) AMMONIUM CHLORIDE (UNII: 01Q9PC255D) CALCIUM SULFATE (UNII: WATO DDB505) CALCIUM SULFATE (UNII: W69379FGK) ARNICA MONTANA (UNII: 080TY208ZW) ELM (UNII: 63POE2M46 Y) STELLARIA MEDIA (UNII: 2H03479QVR) COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	EUCALYPTUS OIL (UNII: 2R04ONI662)	
PATCHOULI OIL (UNII: F3IN55X5PO) GINGER OIL (UNII: SAS9 Z1S VUK) SAGE OIL (UNII: U27K0 HIH2O) OREGANO (UNII: 0E5AT8T16 U) GLUCOSAMINE (UNII: N08 U5BOQ 1K) CHONDRO ITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z) LITHIUM CHLORIDE (UNII: 649 62 Q A067) POTASSIUM CHLORIDE (UNII: 660 YQ98110) CUPRIC SULFATE ANHYDROUS (UNII: KUW2Q3U1VV) AMMONIUM CHLORIDE (UNII: 019 PC255D) CALCIUM SULFATE (UNII: WATO DDB505) CALCIUM SULFATE (UNII: H0G9379 FGK) ARNICA MONTANA (UNII: 698 TY208 ZW) ELM (UNII: 63POE2M46 Y) STELLARIA MEDIA (UNII: 2H03479 QVR) COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2Z419 WNO6 U) GREEN TEA LEAF (UNII: W2Z4178B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
GINGER OIL (UNII: SAS9ZISVUK) SAGE OIL (UNII: U27K0HIH2O) OREGANO (UNII: 0E5AT8T16U) GLUCOSAMINE (UNII: N08U5BOQ1K) CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z) LITHIUM CHLORIDE (UNII: 64962QA067) POTASSIUM CHLORIDE (UNII: 660YQ981I0) CUPRIC SULFATE ANHYDROUS (UNII: KUW2Q3U1VV) AMMONIUM CHLORIDE (UNII: 01Q9PC255D) CALCIUM SULFATE (UNII: WAT0 DDB505) CALCIUM SULFATE (UNII: WAT0 DDB505) CALCIUM CARBONATE (UNII: 1069379FGK) ARNICA MONTANA (UNII: 080TY208ZW) ELM (UNII: 63POE2M46Y) STELLARIA MEDIA (UNII: 2H03479QVR) COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2469WN06U) GREEN TEA LEAF (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	ROSEMARY OIL (UNII: 8LGU7VM393)	
SAGE OIL (UNII: U27K0HIH2O) OREGANO (UNII: 0E5AT8T16U) GLUCOSAMINE (UNII: N08U5BOQ1K) CHONDRO ITIN SULFATE (BO VINE) (UNII: 6IC1M3OG5Z) LITHIUM CHLORIDE (UNII: G4962QA067) POTASSIUM CHLORIDE (UNII: 660 YQ98110) CUPRIC SULFATE ANHYDROUS (UNII: KUW2Q3U1VV) AMMONIUM CHLORIDE (UNII: 01Q9PC255D) CALCIUM SULFATE (UNII: WAT0DDB505) CALCIUM SULFATE (UNII: WAT0DDB505) CALCIUM CARBONATE (UNII: H0G9379FGK) ARNICA MONTANA (UNII: 080TY208ZW) ELM (UNII: 63POE2M46Y) STELLARIA MEDIA (UNII: 2H03479QVR) COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2469WNO6U) GREEN TEA LEAF (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	PATCHOULI OIL (UNII: F3IN55X5PO)	
OREGANO (UNII: 0E5AT8T16U) GLUCO SAMINE (UNII: N08U5BOQ1K) CHONDRO ITIN SULFATE (BO VINE) (UNII: 6IC1M3OG5Z) LITHIUM CHLORIDE (UNII: G4962QA067) POTASSIUM CHLORIDE (UNII: 660 YQ98I10) CUPRIC SULFATE ANHYDRO US (UNII: KUW2Q3U1VV) AMMO NIUM CHLORIDE (UNII: 01Q9PC255D) CALCIUM SULFATE (UNII: WAT0 DDB505) CALCIUM SULFATE (UNII: WAT0 DDB505) CALCIUM CARBO NATE (UNII: H0G9379FGK) ARNICA MO NTANA (UNII: 080 TY208 ZW) ELM (UNII: 63POE2M46Y) STELLARIA MEDIA (UNII: 2H03479QVR) COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2469WN06U) GREEN TEA LEAF (UNII: WZZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	GINGER OIL (UNII: SAS9Z1SVUK)	
GLUCO SAMINE (UNII: N08U5BOQ1K) CHONDRO ITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z) LITHIUM CHLORIDE (UNII: G4962QA067) POTASSIUM CHLORIDE (UNII: 660 YQ98I10) CUPRIC SULFATE ANHYDRO US (UNII: KUW2Q3U1VV) AMMO NIUM CHLORIDE (UNII: 01Q9PC255D) CALCIUM SULFATE (UNII: WAT0DDB505) CALCIUM SULFATE (UNII: WAT0DDB505) CALCIUM CARBONATE (UNII: H0G9379FGK) ARNICA MONTANA (UNII: O80TY208ZW) ELM (UNII: 63P0E2M46 Y) STELLARIA MEDIA (UNII: 2H03479QVR) COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2469WNO6U) GREEN TEA LEAF (UNII: W2ZUIRY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	SAGE OIL (UNII: U27K0H1H2O)	
CHONDROITIN SULFATE (BO VINE) (UNII: 6IC1M3OG5Z) LITHIUM CHLORIDE (UNII: G4962QA067) POTASSIUM CHLORIDE (UNII: 660 YQ98 II0) CUPRIC SULFATE ANHYDRO US (UNII: KUW2Q3U1VV) AMMO NIUM CHLORIDE (UNII: 01Q9PC255D) CALCIUM SULFATE (UNII: WAT0DDB505) CALCIUM CARBONATE (UNII: H0G9379FGK) ARNICA MONTANA (UNII: 080TY208 ZW) ELM (UNII: 63P0E2M46 Y) STELLARIA MEDIA (UNII: 2H03479 QVR) COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2469WNO6U) GREEN TEA LEAF (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	OREGANO (UNII: 0E5AT8T16U)	
LITHIUM CHLO RIDE (UNII: G4962QA067) PO TASSIUM CHLO RIDE (UNII: 660 YQ98110) CUPRIC SULFATE ANHYDRO US (UNII: KUW2Q3U1VV) AMMO NIUM CHLO RIDE (UNII: 01Q9PC255D) CALCIUM SULFATE (UNII: WAT0 DDB505) CALCIUM CARBONATE (UNII: H0 G9379 FGK) ARNICA MONTANA (UNII: 080 TY208 ZW) ELM (UNII: 63POE2M46Y) STELLARIA MEDIA (UNII: 2H03479 QVR) COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: 015HXK6R3G) MYRRH (UNII: 01673H6H83) PLANTAGO MAJOR (UNII: W2469 WNO6U) GREEN TEA LEAF (UNII: W2ZU1RY8 B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	GLUCOSAMINE (UNII: N08U5BOQ1K)	
PO TASSIUM CHLO RIDE (UNII: 660 YQ 98110) CUPRIC SULFATE ANHYDRO US (UNII: KUW2Q3U1VV) AMMO NIUM CHLO RIDE (UNII: 01Q9 PC255D) CALCIUM SULFATE (UNII: WAT0 DDB505) CALCIUM CARBONATE (UNII: H0 G9379 FGK) ARNICA MONTANA (UNII: 080 TY20 8 ZW) ELM (UNII: 63PO E2 M46 Y) STELLARIA MEDIA (UNII: 2H0 3479 QVR) COMFREY (UNII: D05HXK6 R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6 H83) PLANTAGO MAJOR (UNII: W2469 WNO6 U) GREEN TEA LEAF (UNII: W2ZU1RY8 B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
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AMMONIUM CHLORIDE (UNII: 01Q9PC255D) CALCIUM SULFATE (UNII: WAT0DDB505) CALCIUM CARBONATE (UNII: H0G9379FGK) ARNICA MONTANA (UNII: 080TY208ZW) ELM (UNII: 63POE2M46Y) STELLARIA MEDIA (UNII: 2H03479QVR) COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2469WNO6U) GREEN TEA LEAF (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	POTASSIUM CHLORIDE (UNII: 660 YQ98 I10)	
CALCIUM SULFATE (UNII: WAT0 DDB 505) CALCIUM CARBONATE (UNII: H0 G9 379 FGK) ARNICA MONTANA (UNII: 080 TY208 ZW) ELM (UNII: 63POE2M46 Y) STELLARIA MEDIA (UNII: 2H0 3479 QVR) COMFREY (UNII: D0 5HXK6 R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6 H83) PLANTAGO MAJOR (UNII: W2469 WNO6 U) GREEN TEA LEAF (UNII: W2ZU1RY8 B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	CUPRIC SULFATE ANHYDRO US (UNII: KUW2Q3U1VV)	
CALCIUM CARBONATE (UNII: H0 G9379 FGK) ARNICA MONTANA (UNII: O80 TY208 ZW) ELM (UNII: 63PO E2M46 Y) STELLARIA MEDIA (UNII: 2H0 3479 QVR) COMFREY (UNII: D0 5HXK6 R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6 H83) PLANTAGO MAJOR (UNII: W2469 WNO6 U) GREEN TEA LEAF (UNII: W2ZU1RY8 B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	AMMO NIUM CHLO RIDE (UNII: 01Q9PC255D)	
ARNICA MONTANA (UNII: O80TY208ZW) ELM (UNII: 63POE2M46Y) STELLARIA MEDIA (UNII: 2H03479QVR) COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2469WNO6U) GREEN TEA LEAF (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	CALCIUM SULFATE (UNII: WAT0 DDB505)	
ELM (UNII: 63POE2M46 Y) STELLARIA MEDIA (UNII: 2H03479 QVR) COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2469 WNO 6 U) GREEN TEA LEAF (UNII: W2ZU1RY8 B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	CALCIUM CARBONATE (UNII: H0 G9 379 FGK)	
STELLARIA MEDIA (UNII: 2H03479QVR) COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2469WNO6U) GREEN TEA LEAF (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	ARNICA MONTANA (UNII: O80 TY20 8 ZW)	
COMFREY (UNII: D05HXK6R3G) MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2469WNO6U) GREEN TEA LEAF (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	ELM (UNII: 63POE2M46Y)	
MYRRH (UNII: JC71GJ1F3L) HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2469WNO6U) GREEN TEA LEAF (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	STELLARIA MEDIA (UNII: 2H0 3479 QVR)	
HOPS (UNII: 01G73H6H83) PLANTAGO MAJOR (UNII: W2469WNO6U) GREEN TEA LEAF (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	COMFREY (UNII: D05HXK6R3G)	
PLANTAGO MAJOR (UNII: W2469WNO6U) GREEN TEA LEAF (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	MYRRH (UNII: JC71GJ1F3L)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	HOPS (UNII: 01G73H6H83)	
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	PLANTAGO MAJOR (UNII: W2469WNO6U)	
	GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	
	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62001-0318-1	318880.8 g in 1 CONTAINER		
2	NDC:62001-0318-2	454 g in 1 CONTAINER		
3	NDC:62001-0318-3	71 g in 1 TUBE, WITH APPLICATOR		
4	NDC:62001-0318-4	113 g in 1 TUBE		
5	NDC:62001-0318-5	4 g in 1 POUCH		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/24/2004	

Labeler - Straight Arrow Products, Inc. (061580593)

Registrant - Straight Arrow Products, Inc. (061580593)

Establishment				
Name	Address	ID/FEI	Business Operations	

Straight Arrow Products, Inc. 061580593 manufacture

Revised: 9/2010 Straight Arrow Products, Inc.