ICY HOT PAIN RELIEVING STICK- menthol and methyl salicylate stick ICY HOT PAIN RELIEVING BALM- menthol and methyl salicylate ointment ICY HOT PAIN RELIEVING CREAM- menthol and methyl salicylate cream Chattem, 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.

Icy Hot

ICYHOT_® PAIN RELIEVING STICK Drug Facts

Active ingredient

Menthol 10% Methyl salicylate 30%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with:

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

Warnings

For external use only

SEE INSIDE LABEL FOR COMPLETE DRUG FACTS

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

When using this product

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged, broken or irritated skin

Stop use and ask a doctor if

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

If pregnant or breast-feeding,

ask a health care 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 12 years:

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but not more than 4 times daily

children 12 years or younger: ask a doctor

Inactive ingredients

ceresin, cyclomethicone, hydrogenated castor oil, microcrystalline wax, paraffin, PEG-150 distearate, propylene glycol, stearic acid, stearyl alcohol (245-111)

$ICYHOT_{\textcircled{B}}$ PAIN RELIEVING BALM Drug Facts

Active ingredient

Menthol 7.6% Methyl salicylate 29%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with:

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

Warnings

For external use only

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

When using this product

- use only as directed
- avoid contact with eyes or mucous membranes
- do not bandage tightly or use with a heating pad
- do not apply to wounds or damaged, broken or irritated skin

Stop use and ask a doctor if

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

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children.

If case of accidental ingestion, get medical help or contact a Poison Control Center right away.

continued on cap

Directions

adults and children over 12 years:

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but not more than 4 times daily

children 12 years or younger: ask a doctor

Inactive ingredients

paraffin, white petrolatum (245-109)

ICYHOT_® PAIN RELIEVING CREAM Drug Facts

Active ingredient

Menthol 10% Methyl salicylate 30%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with:

arthritis

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

Warnings

For external use only

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

When using this product

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged, broken or irritated skin

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 care professional before use.

Keep out of reach of children.

If case of accidental ingestion, get medical help or contact a Poison Control Center right away.

Directions

adults and children over 12 years:

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but not more than 4 times daily

children 12 years or younger: ask a doctor

Inactive ingredients

carbomer, cetyl esters, emulsifying wax, oleth-3 phosphate, stearic acid, triethanolamine, water (245-110)

Close cap tightly after use.

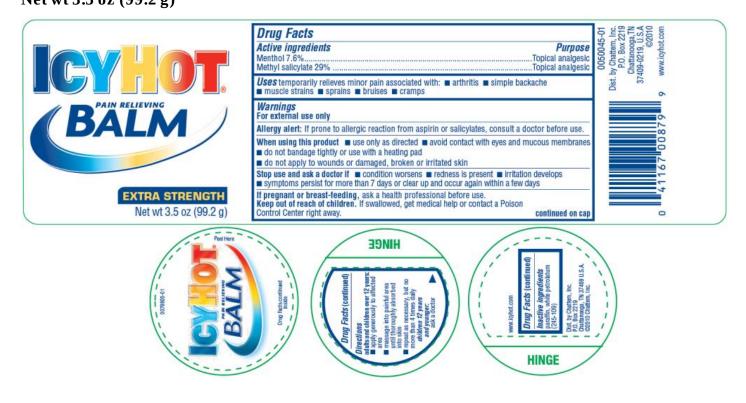
PRINCIPAL DISPLAY PANEL

ICYHOT_® PAIN RELIEVING STICK EXTRA STRENGTH PAIN RELIEVING STICK Net wt 1.75 oz (49 g)



PRINCIPAL DISPLAY PANEL

ICYHOT_® PAIN RELIEVING BALM EXTRA STRENGTH Net wt 3.5 oz (99.2 g)



PRINCIPAL DISPLAY PANEL

 $ICYHOT_{\textcircled{B}}$ PAIN RELIEVING CREAM Net wt 1.25 oz (35.4 g) EXTRA STRENGTH



menthol and methyl salicylate stick

Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source	2)	NDC:41167-	-0089
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
Ing	redient Name		Basis of S	Strength	Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)	METHYL SALICYLAT	TE 30 g in 100 g
Inactive Ingredients		
Ingredient Name		Strength
Ingredient Name CERESIN (UNII: Q1LS2UJO3A)		Strength
Ŭ		Strength
CERESIN (UNII: Q1LS2UJO3A)		Strength
CERESIN (UNII: Q1LS2UJO3A) CYCLOMETHICONE (UNII: NMQ347994Z)		Strength

PEG-150 DISTEARATE (UNII: 6F36Q010AC)PROPYLENE GLYCOL (UNII: 6DC9Q167V3)STEARIC ACID (UNII: 4ELV7Z65AP)

STEARYL ALCOHOL (UNII: 2KR89I4H1Y)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0089-8	49 g in 1 JAR; Type 0: Not a Combination Product	06/01/1991	

Marketing Information

 Marketing Category
 Application Number or Monograph Octation
 Marketing Start Oct
 Marketing Category

 OTC MONOGRAPHNOT FINAL
 par348
 06/01/091
 06/01/091

ICY HOT PAIN RELIEVING BALM

menthol and methyl salicylate ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0087
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	7.6 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	29 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
PARAFFIN (UNII: 1900E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	

1	Item Code		Package Description	Marketing	Start Date	Marketi	ng End Date
	NDC:41167-0087-9	99 g in 1 JAR;	Type 0: Not a Combination Produ	ct 06/01/1991			
N	Aarketing Info	ormation					
	Marketing Categ		ication Number or Monograp	h Citation Marke	ting Start Da	te Marke	ting End Da
С	TC MONOGRAPH NO			06/01/1	-		
		-					
(CY HOT PAI	N RELIEV	/ING CREAM				
ne	enthol and methyl s	salicylate crea	m				
_							
Р	Product Informat	tion					
	Product Type		HUMAN OTC DRUG	Item Code (Sourc	e)	NDC:41167	7-0088
					-)	1100.41107	-0000
К	Route of Administra	tion	TOPICAL				
•	а .	/A B					
4	ctive Ingredient						<u>.</u>
		-	gredient Name		Basis of St	rength	Strength
			HOL - UNII:L7T10EIP3A)		MENTHOL		10 g in 100
IVI	ETHYL SALICYLAT	E (UNII: LAV50	5022Y) (SALICYLIC ACID - UNII:	U414PZ4LPZ)	METHYL SAL	IC YLATE	30 g in 100
т.	nactive Ingredie	nts					
			In and is at Name			64	rength
			Ingredient Name			31	rengtin
	ETYL ESTERS WAX	(UNII: D072FFP	Ingredient Name 9GU)			51	rengtn
C	ETYL ESTERS WAX LETH-3 PHOSPHAT		9GU)			51.	rengtn
C: 0		E (UNII: 8Q0Z1	9GU)			51	rengtn
C: 0 S':	LETH-3 PHO SPHAT	E (UNII: 8Q0Z1 4ELV7Z65AP)	9GU)			51	rengtn
C: 0 S': W	LETH-3 PHOSPHAT TEARIC ACID (UNII: 4	E (UNII: 8Q0Z18 4ELV7Z65AP) KO0R)	9GU)			51	rengtn
C: 0 S': W	LETH-3 PHO SPHAT TEARIC ACID (UNII: 4 /ATER (UNII: 059QF0	E (UNII: 8Q0Z18 4ELV7Z65AP) KO0R)	9GU)			51	rengtn
C: 0 S': W	LETH-3 PHO SPHAT TEARIC ACID (UNII: 4 /ATER (UNII: 059QF0	E (UNII: 8Q0Z18 4ELV7Z65AP) KO0R)	9GU)			51	rengtn
C: 0 S': W	LETH-3 PHO SPHAT TEARIC ACID (UNII: 4 /ATER (UNII: 059QF0	E (UNII: 8Q0Z18 4ELV7Z65AP) KO0R)	9GU)			51	
	LETH-3 PHOSPHAT TEARIC ACID (UNII: 4 ATER (UNII: 059QF0 ROLAMINE (UNII: 9C Packaging	E (UNII: 8Q0Z1 4ELV7Z65AP) KO0R) 03K93S3TK)	9GU)	Marketin	g Start Date		
C: S': W T': P	LETH-3 PHOSPHAT TEARIC ACID (UNII: 4 ATER (UNII: 059QF0 ROLAMINE (UNII: 9C Cackaging	E (UNII: 8Q0Z1 4ELV7Z65AP) KO0R) 03K93S3TK)	9GU) 3J1VL) Package Description	Marketin 06/01/1991	g Start Date		
C: S': W T! P #	LETH-3 PHOSPHAT TEARIC ACID (UNII: ATER (UNII: 059QF0 ROLAMINE (UNII: 9C Packaging Item Code	E (UNII: 8Q0Z1 4ELV7Z65AP) KO0R) 03K93S3TK) 1 in 1 CARTON	9GU) 3J1VL) Package Description	06/01/1991	g Start Date		
C: S: W T: P #	LETH-3 PHOSPHAT TEARIC ACID (UNII: ATER (UNII: 059QF0 ROLAMINE (UNII: 9C Packaging Item Code	E (UNII: 8Q0Z1 4ELV7Z65AP) KO0R) 03K93S3TK) 1 in 1 CARTON	9GU) 3J1VL) Package Description ; Type 0: Not a Combination Prod	06/01/1991	g Start Date		
C: O S': W T': P # 1 1 2	LETH-3 PHOSPHAT TEARIC ACID (UNII: 4 ATER (UNII: 059QF0 ROLAMINE (UNII: 9C Cackaging Item Code NDC:41167-0088-1	E (UNII: 8Q0Z1 4ELV7Z65AP) KO0R) D3K93S3TK) 1 in 1 CARTON 85 g in 1 TUBE 1 in 1 CARTON	9GU) 3J1VL) Package Description ; Type 0: Not a Combination Prod	06/01/1991 uct 06/01/1991	g Start Date		
C: O S': W T': P # 1 1 2 2	LETH-3 PHOSPHAT TEARIC ACID (UNII: 4 ATER (UNII: 059QF0 ROLAMINE (UNII: 9C Cackaging Item Code NDC:41167-0088-1	E (UNII: 8Q0Z1 4ELV7Z65AP) KO0R) O3K93S3TK) 1 in 1 CARTON 85 g in 1 TUBE 1 in 1 CARTON 35.4 g in 1 TUB 1 in 1 CARTON	9GU) 3J1VL) Package Description ; Type 0: Not a Combination Prod E; Type 0: Not a Combination Pro	06/01/1991 uct 06/01/1991 duct 06/01/1991	g Start Date		
C: O S': W T': P # 1 1 2 2	LETH-3 PHO SPHAT TEARIC ACID (UNII: 4 ATER (UNII: 059QF0 ROLAMINE (UNII: 9C CACKAGING Item Code NDC:41167-0088-1	E (UNII: 8Q0Z1 4ELV7Z65AP) KO0R) O3K93S3TK) 1 in 1 CARTON 85 g in 1 TUBE 1 in 1 CARTON 35.4 g in 1 TUB 1 in 1 CARTON	9GU) 3J1VL) Package Description ; Type 0: Not a Combination Prod E; Type 0: Not a Combination Prod	06/01/1991 uct 06/01/1991 duct 06/01/1991	g Start Date		
C: 0 S' W T 1 1 1 2 2 3	LETH-3 PHO SPHAT TEARIC ACID (UNII: 4 ATER (UNII: 059QF0 ROLAMINE (UNII: 9C CACKAGING Item Code NDC:41167-0088-1	E (UNII: 8Q0Z1 4ELV7Z65AP) KO0R) O3K93S3TK) 1 in 1 CARTON 85 g in 1 TUBE 1 in 1 CARTON 35.4 g in 1 TUB 1 in 1 CARTON	9GU) 3J1VL) Package Description ; Type 0: Not a Combination Prod E; Type 0: Not a Combination Pro	06/01/1991 uct 06/01/1991 duct 06/01/1991	g Start Date		
C: D S: P # L L L 2 2 3	LETH-3 PHO SPHAT TEARIC ACID (UNII: 4 ATER (UNII: 059QF0 ROLAMINE (UNII: 9C CACKAGING Item Code NDC:41167-0088-1	E (UNII: 8Q0Z1 4ELV7Z65AP) KO0R) O3K93S3TK) 1 in 1 CARTON 85 g in 1 TUBE 1 in 1 CARTON 35.4 g in 1 TUB 1 in 1 CARTON	9GU) 3J1VL) Package Description ; Type 0: Not a Combination Prod E; Type 0: Not a Combination Pro	06/01/1991 uct 06/01/1991 duct 06/01/1991	g Start Date		

Labeler - Chattem, Inc. (003336013)

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Chattem, Inc.