

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. Read and follow all directions and warnings on this label.
- avoid contact with eyes and mucous membranes

- rare cases of serious burns have been reported with products of this type
- do not apply to wounds or damaged, broken or irritated skin
- do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use
- a transient burning sensation may occur upon application but generally disappears in several days
- if severe burning sensation occurs, discontinue use immediately
- do not expose the area treated with product to heat or direct sunlight

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 a thin layer 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® 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. Read and follow all directions and warnings on this label.
- avoid contact with eyes and mucous membranes
- rare cases of serious burns have been reported with products of this type
- do not apply to wounds or damaged, broken or irritated skin
- do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use
- do not use at the same time as other topical analgesics
- a transient burning sensation may occur upon application but generally disappears in several days
- if severe burning sensation occurs, discontinue use immediately
- do not expose the area treated with product to heat or direct sunlight
- avoid applying into skin folds

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
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

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 right away.

Directions

adults and children over 12 years:

- apply a thin layer to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 4 times daily
- **AFTER APPLYING, WASH HANDS WITH SOAP AND WATER**

children 12 years or younger: ask a doctor

Inactive ingredients

paraffin, white petrolatum

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. Read and follow all directions and warnings on this carton.
- avoid contact with eyes and mucous membranes
- rare cases of serious burns have been reported with products of this type
- do not apply to wounds or damaged, broken or irritated skin
- do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use
- do not use at the same time as other topical analgesics
- a transient burning sensation may occur upon application but generally disappears in several days
- if severe burning sensation occurs, discontinue use immediately
- do not expose the area treated with product to heat or direct sunlight
- avoid applying into skin folds

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
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

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 right away.

Directions

adults and children over 12 years:

- apply a thin layer to affected area
 - massage into painful area until thoroughly absorbed into skin
 - repeat as necessary, but no more than 4 times daily
 - **AFTER APPLYING, WASH HANDS WITH SOAP AND WATER**
- children 12 years or younger: ask a doctor**

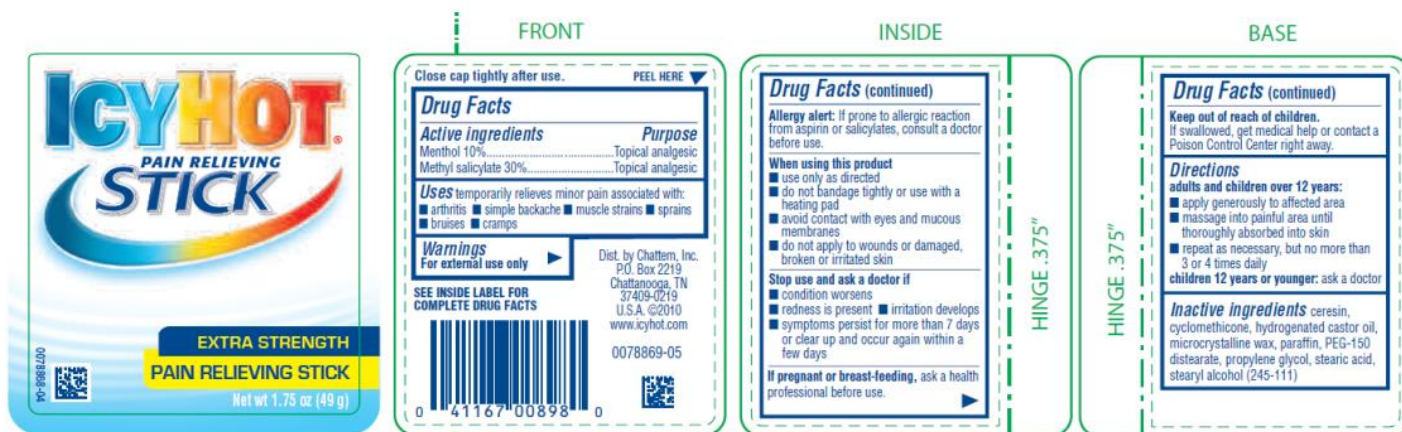
Inactive ingredients

carbomer, cetearyl alcohol, cetyl esters, oleth-3 phosphate, polysorbate 60, stearic acid, triethanolamine, water

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
Net wt 3.5 oz (99.2 g)**



**PAIN RELIEF
BALM**

NET WT 3.5 OZ (99.2 g)

Drug Facts

Active ingredients

Menthol 7.6%

Methyl salicylate 29%

Purpose

Topical analgesic

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. Read and follow all directions and warnings on this label.
■ avoid contact with eyes and mucous membranes ■ rare cases of serious burns have been reported with products of this type ■ do not apply to wounds or damaged, broken or irritated skin ■ do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use ■ do not use at the same time as other topical analgesics ■ a transient burning sensation may occur upon application but generally disappears in several days ■ if severe burning sensation occurs, discontinue use immediately ■ do not expose the area treated with product to heat or direct sunlight ■ avoid applying into skin folds

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 ■ you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

continued on cap

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TOP

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ICYHOT
ORIGINAL

Print Here

**PAIN RELIEF
BALM**

Drug Facts continued inside

INSIDE TOP

Drug Facts (continued)

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 right away.

Directions

adults and children over 12 years:

- apply a thin layer to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 4 times daily

BASE

Drug Facts (continued)

■ **AFTER APPLYING, WASH HANDS WITH SOAP AND WATER**
children 12 years and younger:
ask a doctor

Inactive ingredients
paraffin, white petrolatum

Close cap tightly between uses.

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CHATTEM

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PRINCIPAL DISPLAY PANEL

ICYHOT® PAIN RELIEVING CREAM
Net wt 1.25 oz (35.4 g)



Drug Facts
Active ingredients
Menthol 10%
Methyl salicylate 30%
Purpose
Warnings
Directions
Inactive ingredients

ICYHOT ORIGINAL

MENTHOL 10% + METHYL SALICYLATE 30%

NEW LOOK

ICYHOT ORIGINAL

PAIN RELIEF CREAM
FEEL IT WORKING INSTANTLY



- ▶ Powerful Pain Relief for Muscles and Joints
- ▶ Icy to Dull, Hot to Relax
- ▶ Non-Greasy

NET WT 1.25 OZ (35.4 g)

ICYHOT ORIGINAL

TARGETED RELIEF FOR

- ▶ Simple Backache
- ▶ Sprains
- ▶ Muscle Strains
- ▶ Bruises

PLEASE READ AND UNDERSTAND THE DRUG FACTS BEFORE USING.
 Close cap tightly after use.

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 A SANOFI COMPANY



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MENTHOL 10% + METHYL SALICYLATE 30%

NEW LOOK

ICYHOT ORIGINAL

PAIN RELIEF CREAM

FEEL IT WORKING INSTANTLY

- ▶ Powerful Pain Relief for Muscles and Joints
- ▶ Icy to Dull, Hot to Relax
- ▶ Non-Greasy

NET WT 1.25 OZ (35.4 g)

ICYHOT ORIGINAL

ICY HOT PAIN RELIEVING STICK

menthol and methyl salicylate stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0089
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
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 Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/1991	

ICY HOT PAIN RELIEVING BALM

menthol and methyl salicylate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0087
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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: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0087-9	99 g in 1 JAR; Type 0: Not a Combination Product	06/01/1991	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/1991	

ICY HOT PAIN RELIEVING CREAM

menthol and methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0088
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ESTERS WAX (UNII: D072FFP9GU)	

OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)

STEARIC ACID (UNII: 4ELV7Z65AP)

WATER (UNII: 059QF0KO0R)

TROLAMINE (UNII: 9O3K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0088-1	1 in 1 CARTON	06/01/1991	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:41167-0088-5	1 in 1 CARTON	06/01/1991	
2		35.4 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:41167-0088-8	1 in 1 CARTON	06/01/1991	
3		44 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	06/01/1991	

Labeler - Chattem, Inc. (003336013)

Revised: 3/2021

Chattem, Inc.