CARMEX VARIETY PACK CLASSIC MEDICATED LIP BALM LIP BALM SPF 15-camphor (synthetic), white petrolatum, octinoxate, oxybenzone Carma Laboratories, Inc.

Carmex Variety Pack Classic Medicated Lip Balm Lip Balm SPF 15

Drug Facts

Active ingredients

Camphor 1.70%

White Petrolatum 45.30%

Purpose

External Analgesic

Lip Protectant

Uses

helps provide relief of symptoms of cold sores and dry lips

Warnings

For external use only

When using this product:

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if:

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Do not use

- deep puncture wounds
- serious burns
- animal bites

Keep out of reach of children.

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

Directions

• apply to lips not more than 3 to 4 times daily

• children under 2 years of age: ask a doctor

Other information

• this is a personal care item, and should be used by one individual only

Inactive ingredients

lanolin, beeswax, cetyl esters, paraffinum liquidum, theobroma cacao seed butter, menthol, salicylic acid, phenol, vanillin, flavor

Drug Facts

Active ingredients

Octinoxate 7.50%

Oxybenzone 4.00%

White Petrolatum 35.00%

Purpose

Sunscreen

Lip Protectant

Uses

- helps protect against sunburn and chapped lips
- higher SPF gives more sunburn protection

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

For external use only

Do not use

on damaged or broken skin

When using this product:

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if:

rash occurs

Keep out of reach of children.

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

Directions

- apply liberally 15 minutes before sun exposure
- reapply: at least every 2 hours
- children under 2 years of age: ask a doctor

Other information

- this is a personal care item, and should be used by one individual only
- protect this product from excessive heat and direct sun
- do not use if safety seal is broken prior to purchase

Inactive ingredients

lanolin, theobroma cacao seed butter, euphorbia cerifera cera, beeswax, cetyl esters, ozokerite, paraffin, limnanthes alba seed oil, camphor, menthol, salicylic acid, phenol, flavor, vanillin

Drug Facts

Active ingredients

White Petrolatum 45.30%

Purpose

Lip Protectant

Uses

helps prevent, protect, and relieve chapped lips

Warnings

For external use only

When using this product:

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if:

condition worsens

• symptoms last more than 7 days or clear up and occur again within a few days

Do not use

- deep puncture wounds
- serious burns
- animal bites

Keep out of reach of children.

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

Directions

apply as needed

Other information

- this is a personal care item, and should be used by one individual only
- protect this product from excessive heat and direct sun

Inactive ingredients

lanolin, beeswax, cetyl esters, paraffin, theobroma cacao seed butter, camphor, menthol, salicylic acid, phenol, vanillin, flavor

Package Labeling:











CARMEX VARIETY PACK CLASSIC MEDICATED LIP BALM LIP BALM SPF 15

camphor (synthetic), white petrolatum, octinoxate, oxybenzone kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10210-0089

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# Ite	m Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:10	210-0089-1	1 in 1 KIT	04/01/2025	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	3 TUBE	30 g
Part 2	3 CYLINDER	12.75 g
Part 3	3 JAR	22.5 g

Part 1 of 3

CARMEX CLASSIC LIP BALM MEDICATED

camphor (synthetic), petrolatum salve

Product Information

Item Code (Source) NDC:10210-0022

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	1.7 g in 100 g		
WHITE PETROLATUM (UNII: B6E5W8RQJ4) (WHITE PETROLATUM - UNII:B6E5W8RQJ4)	WHITE PETROLATUM	45.3 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
LANOLIN (UNII: 7EV65EAW6H)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
CETYL ESTERS WAX (UNII: D072FFP9GU)			
MINERAL OIL (UNII: T5L8T28FGP)			
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)			
SALICYLIC ACID (UNII: O414PZ4LPZ)			
PHENOL (UNII: 339NCG44TV)			
VANILLIN (UNII: CHI530446X)			
COCOA BUTTER (UNII: 5120YT1CRR)			

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:10210- 0022-6	10 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M017	04/01/2025	

Part 2 of 3

CARMEX CLASSIC LIP BALM MEDICATED SPF 15

octinoxate, oxybenzone, petrolatum salve

Product Information

Item Code (Source) NDC:10210-0023

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength OCTINOXATE (UNII: 4Y5P7MUD51) (ETHYLHEXYL METHOXYCINNAMATE - UNII: 4Y5P7MUD51) OCTINOXATE (UNII: 4Y5P7MUD51) OCTINOXATE 7.5 g in 100 g				
O(100000)	Name			
OXYBENZONE (UNII: 9500S7VE0Y) (BENZOPHENONE-3 - UNII:9500S7VE0Y) OXYBENZONE 4 g in 100	OPHENONE-3 - UNII:950OS7VE0Y) OXYBENZONE 4 g in 100 g			
WHITE PETROLATUM (UNII: B6E5W8RQJ4) (WHITE PETROLATUM - UNII: B6E5W8RQJ4) WHITE PETROLATUM 35 g in 100 g	(WHITE PETROLATUM - WHITE PETROLATUM 35 g in 100 g			

Inactive Ingredients			
Ingredient Name	Strength		
LANOLIN (UNII: 7EV65EAW6H)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
CETYL ESTERS WAX (UNII: D072FFP9GU)			
PARAFFIN (UNII: 1900E3H2ZE)			
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)			
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)			
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)			
SALICYLIC ACID (UNII: O414PZ4LPZ)			
PHENOL (UNII: 339NCG44TV)			
VANILLIN (UNII: CHI530446X)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:10210- 0023-1	4.25 g in 1 CYLINDER; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M020	04/01/2025	

Part 3 of 3

CARMEX CLASSIC LIP BALM MEDICATED LIP PROTECTANT

white petrolatum salve

Product Information

Item Code (Source) NDC:10210-0055

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

WHITE PETROLATUM (UNII: B6E5W8RQJ4) (WHITE PETROLATUM - UNII: B6E5W8RQJ4)

WHITE PETROLATUM

453 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
LANOLIN (UNII: 7EV65EAW6H)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
CETYL ESTERS WAX (UNII: D072FFP9GU)			
PARAFFIN (UNII: 1900E3H2ZE)			
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)			
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)			
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)			
SALICYLIC ACID (UNII: O414PZ4LPZ)			
PHENOL (UNII: 339NCG44TV)			
VANILLIN (UNII: CHI530446X)			

l	Packaging								
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
	1	NDC:10210- 0055-1	7.5 g in 1 JAR; Type 0: Not a Combination Product						

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC Monograph Drug	M016	04/01/2025					

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC Monograph Drug	M017	04/01/2025					

Labeler - Carma Laboratories, Inc. (006090153)

Establishment							
Name	Address	ID/FEI	Business Operations				
Carma Laboratories, Inc.		006090153	manufacture(10210-0089, 10210-0022, 10210-0023, 10210-0055)				

Revised: 3/2025 Carma Laboratories, Inc.