CARMEX VARIETY PACK CLASSIC MEDICATED LIP BALM DAILY CARE LIP BALM SPF- camphor (synthetic), white petrolatum octinoxate, oxybenzone, avobenzone, homosalate, octisalate, octocrylene Carma Laboratories, Inc.

Carmex Variety Pack - Classic Medicated Lip Balm, Daily Care Lip Balm SPF

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%

Purpose

Sunscreen

Uses

- helps protect against sunburn
- 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: after 80 minutes of swimming or sweating
- immediately after towel drying 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

petrolatum, lanolin, euphorbia cerifera cera, isopropyl palmitate, ozokerite, flavor, beeswax, cetyl esters, paraffin, theobroma cacao seed butter, limnanthes alba seed oil, stevia rebaudiana extract

Drug Facts

Active Ingredients

Avobenzone (3.0%)

Homosalate (10.0%)

Octisalate (5.0%)

Octocrylene (9.0%)

White Petrolatum (31.0%)

Purpose

Sunscreen

Lip Protectant

Uses

- helps prevent sunburn
- hepls protect against the drying effects of wind
- high SPF gives more sunburn protection
- provides moderate protection against sunburn
- if used as directed with other sun protection measures (see *Directions*), decreases

the risk of skin cancer and early skin aging caused by the sun

Warnings

Do not use

on damaged or broken skin

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

- children under 6 months: Ask a doctor
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses

Inactive ingredients

euphorbia cerifera cera, ozoketite, flavor, paraffin, beeswax, Theobroma cacao seed butter, cetyl esters, lanolin, limnanthes alba seed oil, stevia rebaudiana extract

Package Labeling:













CARMEX VARIETY PACK CLASSIC MEDICATED LIP BALM DAILY CARE LIP BALM SPF

camphor (synthetic), white petrolatum octinoxate, oxybenzone, avobenzone, homosalate, octisalate, octocrylene kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10210-0092

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10210-0092-1	1 in 1 KIT	04/01/2025	

Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	3 TUBE	30 g		
Part 2	1 CYLINDER	4.25 g		
Part 3	1 CYLINDER	4.25 g		
Part 4	2 CYLINDER	8.5 g		

Part 1 of 4

CARMEX CLASSIC LIP BALM MEDICATED

camphor (synthetic), petrolatum salve

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)				

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:10210- 0022-6	10 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 Drug	M017	04/01/2025			

Part 2 of 4

CARMEX DAILY CARE MOISTURIZING LIP BALM FRESH CHERRY SPF 15

octinoxate, oxybenzone salve

Product Information

Item Code (Source) NDC:10210-0028

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (ETHYLHEXYL METHOXYCINNAMATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g	
OXYBENZONE (UNII: 9500S7VE0Y) (BENZOPHENONE-3 - UNII:9500S7VE0Y)	OXYBENZ ONE	40 mg in 1 g	

Inactive Ingredients				
Ingredient Name	Strength			
PETROLATUM (UNII: 4T6H12BN9U)				
LANOLIN (UNII: 7EV65EAW6H)				
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)				
YELLOW WAX (UNII: 2ZA36H0S2V)				
CETYL ESTERS WAX (UNII: D072FFP9GU)				
PARAFFIN (UNII: 1900E3H2ZE)				
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:10210- 0028-1	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		

Part 3 of 4

CARMEX DAILY CARE MOISTURIZING LIP BALM STRAWBERRY SPF 15

octinoxate, oxybenzone salve

Product Information

Item Code (Source) NDC:10210-0031

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OCTINOXATE (UNII: 4Y5P7MUD51) (ETHYLHEXYL METHOXYCINNAMATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g		
OXYBENZONE (UNII: 9500S7VE0Y) (BENZOPHENONE-3 - UNII:9500S7VE0Y)	OXYBENZONE	40 mg in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
PETROLATUM (UNII: 4T6H12BN9U)			
LANOLIN (UNII: 7EV65EAW6H)			
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
CETYL ESTERS WAX (UNII: D072FFP9GU)			
PARAFFIN (UNII: 1900E3H2ZE)			
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)			

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:10210- 0031-1	4.25 g in 1 CYLINDER; Type 0: Not a Combination Product		

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

Part 4 of 4

CARMEX WEATHER GUARD MOISTURIZING LIP BALM SPF 30

avobenzone, homosalate, octisalate, octocrylene, white petrolatum salve

Product Information

Item Code (Source) NDC:10210-0056

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g	
OCTISALATE (UNII: 4X49Y0596W) (ETHYLHEXYL SALICYLATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	90 mg in 1 g	
WHITE PETROLATUM (UNII: B6E5W8RQJ4) (WHITE PETROLATUM - UNII: B6E5W8RQJ4)	WHITE PETROLATUM	310 mg in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
PARAFFIN (UNII: 1900E3H2ZE)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
CETYL ESTERS WAX (UNII: D072FFP9GU)			
LANOLIN (UNII: 7EV65EAW6H)			
MEADOWFOAM SEED OIL (UNII: 412Z HA4T4Y)			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:10210- 0056-1	1 in 1 CARTON			
1	4.25 g in 1 CYLINDER; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	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(10210-0092, 10210-0022, 10210-0028, 10210-0031, 10210-0056)

Revised: 3/2025 Carma Laboratories, Inc.