

**BLISTEX MEDICATED LIP BALM VARIETY PACK (BLISTEX MEDICATED BERRY LIP BALM, BLISTEX MEDICATED LIP BALM, BLISTEX MEDICATED LIP)-  
dimethicone, octinoxate, octisalate, camphor (synthetic), menthol,  
unspecified form, and phenol  
Blistex Inc**

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**Blistex® Medicated Lip Balm Variety Pack (Blistex® Medicated Berry Lip Balm,  
Blistex® Medicated Lip Balm, Blistex® Medicated Lip Ointment)**

**MEDICATED BERRY BALM**

***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
Dimethicone 2.0% (w/w)	Lip protectant
Octinoxate 6.6% (w/w)	Sunscreen
Octisalate 4.4% (w/w)	Sunscreen

**Uses**

- temporarily protects and helps relieve chapped or cracked lips
- helps prevent sunburn

**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
- use a water resistant sunscreen if swimming or sweating
- children under 6 months of age: Ask a doctor

**Other information**

- protect the product in this container from excessive heat and direct sun

## Inactive ingredients

beeswax, camphor, cetyl alcohol, cetyl palmitate, euphorbia cerifera (candelilla) wax, flavor, isopropyl myristate, lanolin, lanolin oil, menthol, mineral oil, ozokerite, paraffin, petrolatum, phenoxyethanol, polybutene, red 6 lake, theobroma cacao (cocoa) seed butter, titanium dioxide

## MEDICATED LIP BALM

### Drug Facts

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Dimethicone 2.0 % (w/w)	Lip protectant
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- temporarily protects and helps relieve chapped or cracked lips
- helps prevent sunburn

### Warnings

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### Directions

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
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- children under 6 months of age: Ask a doctor

### Other information

- protect the product in this container from excessive heat and direct sun

## Inactive ingredients

beeswax, camphor, cetyl alcohol, cetyl palmitate, euphorbia cerifera (candelilla) wax, flavor, isopropyl myristate, lanolin, lanolin oil, menthol, methyl salicylate, mineral oil, ozokerite, paraffin, petrolatum, phenoxyethanol, polybutene, red 6 lake, theobroma cacao (cocoa) seed butter, titanium dioxide

## MEDICATED LIP OINTMENT

### Drug Facts

<b>Active ingredients</b>	<b>Purpose</b>
Camphor 0.5% (w/w)	External analgesic
Dimethicone 1.1% (w/w)	Lip protectant
Menthol 0.625% (w/w)	External analgesic
Phenol 0.5% (w/w)	External analgesic

### Uses

- for the temporary relief of pain and itching associated with minor lip irritation or cold sores
- temporarily protects and helps relieve chapped or cracked lips

### Warnings

#### For external use only

#### Do not use on

- deep or puncture wounds
- animal bites
- serious burns

#### When using this product

- do not get into eyes
- do not apply over large areas of the body or bandage

#### 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

#### Keep out of reach of children.

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

### Directions

- adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily

- children under 2 years of age: Consult a doctor

### **Inactive ingredients**

allantoin, ammonium hydroxide, beeswax, calcium disodium EDTA, calcium hydroxide, cetyl alcohol, flavors, glycerin, hydrated silica, lanolin, lauric acid, mineral oil, myristic acid, oleic acid, palmitic acid, paraffin, petrolatum, polyglyceryl-3 diisostearate, potassium hydroxide, purified water, SD alcohol 36, sodium hydroxide, sodium saccharin, stearyl alcohol

### **PRINCIPAL DISPLAY PANEL - Kit Carton**

Blistex® MEDICATED VARIETY PACK

Helps heal, soothe  
& protect

There's No Bliss Like Blistex®

# **Blistex** MEDICATED VARIETY PACK

*Helps heal, soothe  
& protect*



**Your Best Lips Begin With Blistex**

*There's No Bliss Like Blistex®*

## MEDICATED LIP BALM



<b>Drug Facts</b>	<b>Active ingredients Purpose</b> Dimethicone 2.0% (w/w) Lip protectant Octinoxate 6.6% (w/w) Sunscreen Octisalate 4.4% (w/w) Sunscreen
<b>Uses</b>	<ul style="list-style-type: none"> <li>temporarily protects and helps relieve chapped or cracked lips</li> <li>helps prevent sunburn</li> </ul>
<b>Warnings</b>	<b>Skin Cancer/Skin Aging Alert:</b> 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.
<b>For external use only</b>	<b>Do not use on</b> damaged or broken skin
<b>When using this product</b>	keep out of eyes. Rinse with water to remove.
<b>Stop use and ask a doctor</b>	if rash occurs
<b>Keep out of reach of children.</b>	If swallowed, get medical help or contact a Poison Control Center right away.
<b>Directions</b>	<ul style="list-style-type: none"> <li>apply liberally 15 minutes before sun exposure</li> <li>reapply at least every 2 hours</li> <li>use a water resistant sunscreen if swimming or sweating</li> <li>children under 6 months of age: Ask a doctor</li> </ul>

Medicated Lip Balm helps prevent dryness and chapping. Its easy glide formula also soothes irritated lips.

### Drug Facts (continued)

**Other information**

- protect the product in this container from excessive heat and direct sun

### Inactive ingredients

beeswax, camphor, cetyl alcohol, cetyl palmitate, euphorbia cerifera (candelilla) wax, flavor, isopropyl myristate, lanolin, lanolin oil, menthol, methyl salicylate, mineral oil, ozokerite, paraffin, petrolatum, phenoxyethanol, polybutene, red 6 lake, theobroma cacao (cocoa) seed butter, titanium dioxide

## MEDICATED LIP OINTMENT



<b>Drug Facts</b>	<b>Active ingredients Purpose</b> Camphor 0.5% (w/w) External analgesic Dimethicone 1.1% (w/w) Lip protectant Menthol 0.625% (w/w) External analgesic Phenol 0.5% (w/w) External analgesic
<b>Uses</b>	<ul style="list-style-type: none"> <li>for the temporary relief of pain and itching associated with minor lip irritation or cold sores</li> <li>temporarily protects and helps relieve chapped or cracked lips</li> </ul>
<b>Warnings</b>	<b>For external use only</b>
<b>Do not use on:</b>	<ul style="list-style-type: none"> <li>deep or puncture wounds</li> <li>animal bites</li> <li>serious burns</li> </ul>
<b>When using this product:</b>	<ul style="list-style-type: none"> <li>do not get into eyes</li> <li>do not apply over large areas of the body or bandage</li> </ul>
<b>Stop use and ask a doctor if:</b>	<ul style="list-style-type: none"> <li>condition worsens</li> <li>symptoms last more than 7 days or clear up and occur again within a few days</li> </ul>
<b>Keep out of reach of children.</b>	If swallowed, get medical help or contact a Poison Control Center right away.
<b>Directions</b>	<ul style="list-style-type: none"> <li>adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily</li> <li>children under 2 years of age: Consult a doctor</li> </ul>

Clinically Shown To Help Heal Dry, Chapped Lips

An Advanced Lip Care System® that delivers penetrating medication in a unique formula to relieve cold sores & severe lip dryness.

### Drug Facts (continued)

**Inactive ingredients**

allantoin, ammonium hydroxide, beeswax, calcium disodium EDTA, calcium hydroxide, cetyl alcohol, flavors, glycerin, hydrated silica, lanolin, lauric acid, mineral oil, myristic acid, oleic acid, palmitic acid, paraffin, petrolatum, polyglyceryl-3 disostearate, potassium hydroxide, purified water, SD alcohol 36, sodium hydroxide, sodium saccharin, stearyl alcohol

Blistex Inc.

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St. Louis, IL 60522-5392

# Blistex® MEDICATED VARIETY PACK

# MEDICATED BERRY BALM



Medicated Berry Lip Balm helps prevent dryness and chapping. Its easy glide formula also soothes irritated lips.

<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Dimethicone 2.0% (w/w) Lip protectant Octinoxate 6.6% (w/w) Sunscreen Octisalate 4.4% (w/w)	Lip protectant Sunscreen
<b>Uses</b>	
<ul style="list-style-type: none"> <li>temporarily protects and helps relieve chapped or cracked lips</li> <li>helps prevent sunburn</li> </ul>	
<b>Warnings</b>	
<b>Skin Cancer/Skin Aging Alert:</b> 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.	
<b>For external use only</b>	
<b>Do not use</b> on damaged or broken skin	
<b>When using this product</b> keep out of eyes. Rinse with water to remove.	
<b>Stop use and ask a doctor</b> if rash occurs	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>apply liberally 15 minutes before sun exposure</li> <li>reapply at least every 2 hours</li> <li>use a water resistant sunscreen if swimming or sweating</li> <li>children under 6 months of age: Ask a doctor</li> </ul>	
<b>Drug Facts (continued)</b>	
<b>Other information</b>	<ul style="list-style-type: none"> <li>protect the product in this container from excessive heat and direct sun</li> </ul>
<b>Inactive ingredients</b>	beeswax, camphor, cetyl alcohol, cetyl palmitate, euphorbia cerifera (candelilla) wax, flavor, isopropyl myristate, lanolin, lanolin oil, menthol, mineral oil, ozokerite, paraffin, petrolatum, phenoxylethanol, polybutene, red 6 lake, theobroma cacao (cocoa) seed butter, titanium dioxide



## BLISTEX MEDICATED LIP BALM VARIETY PACK (BLISTEX MEDICATED BERRY LIP BALM, BLISTEX MEDICATED LIP BALM, BLISTEX MEDICATED LIP BALM, BLISTEX MEDICATED LIP BALM)

dimethicone, octinoxate, octisalate, camphor (synthetic), menthol, unspecified form, and phenol kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10157-9910
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10157-9910-1	1 in 1 CARTON	02/03/2020	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	1 CYLINDER	4.25 g
<b>Part 2</b>	1 CYLINDER	4.25 g
<b>Part 3</b>	1 TUBE	6 g

# BLISTEX MEDICATED BERRY LIP BALM

dimethicone, octinoxate, and octisalate stick

## Product Information

**Route of Administration** TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Dimethicone</b> (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	2 g in 100 g
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	6.6 g in 100 g
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	4.4 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>LANOLIN OIL</b> (UNII: OVV5IJ58F)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>POLYBUTENE (1400 MW)</b> (UNII: 1NA5AO9GH7)	
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>.ALPHA.,.ALPHA.-DIBROMO-D-CAMPHOR</b> (UNII: F89Z8SAG3O)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>D&amp;C RED NO. 6</b> (UNII: 481744AI4O)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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
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**Part 2 of 3****BLISTEX MEDICATED LIP BALM**

dimethicone, octinoxate, and octisalate stick

**Product Information****Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Dimethicone</b> (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	2 g in 100 g
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	6.6 g in 100 g
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	4.4 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>LANOLIN OIL</b> (UNII: OVV5IJ58F)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>POLYBUTENE (1400 MW)</b> (UNII: 1NA5AO9GH7)	
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>.ALPHA.,.ALPHA.-DIBROMO-D-CAMPHOR</b> (UNII: F89Z8SAG3O)	
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>D&amp;C RED NO. 6</b> (UNII: 481744AI4O)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	M016	02/03/2020	

## Part 3 of 3

### BLISTEX MEDICATED LIP

dimethicone, camphor (synthetic), menthol, unspecified form, and phenol ointment

## Product Information

**Route of Administration** TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Dimethicone</b> (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	1.1 g in 100 g
<b>Camphor (Synthetic)</b> (UNII: 5TJD82A1ET) (Camphor (Synthetic) - UNII:5TJD82A1ET)	Camphor (Synthetic)	0.5 g in 100 g
<b>Menthol, Unspecified Form</b> (UNII: L7T10EIP3A) (Menthol, Unspecified Form - UNII:L7T10EIP3A)	Menthol, Unspecified Form	0.625 g in 100 g
<b>Phenol</b> (UNII: 339NCG44TV) (Phenol - UNII:339NCG44TV)	Phenol	0.5 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>PALMITIC ACID</b> (UNII: 2V16EO95H1)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	

<b>CALCIUM HYDROXIDE</b> (UNII: PF5DZW74VN)	
<b>LAURIC ACID</b> (UNII: 1160N9NU9U)	
<b>MYRISTIC ACID</b> (UNII: 013V7S25AW)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>OLEIC ACID</b> (UNII: 2UMI9U37CP)	
<b>EDETATE CALCIUM DISODIUM ANHYDROUS</b> (UNII: 8U5D034955)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 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	02/03/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M016	02/03/2020	

**Labeler** - Blistex Inc (005126354)

### Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc		005126354	MANUFACTURE(10157-9910)

Revised: 12/2024

Blistex Inc