

**BLISTEX MEDICATED LIP BALM VARIETY PACK (BLISTEX MEDICATED BERRY LIP BALM, BLISTEX MEDICATED LIP BALM, BLISTEX MEDICATED MINT LIP BALM)-
dimethicone, octinoxate, and octisalate
Blistex 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.

Blistex® Medicated Lip Balm Variety Pack (Blistex® Medicated Berry Lip Balm, Blistex® Medicated Lip Balm, Blistex® Medicated Mint Lip Balm)

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
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, flavors, isopropyl myristate, lanolin, lanolin oil, menthol, methyl salicylate¹, mineral oil, ozokerite, paraffin,

petrolatum, phenoxyethanol, polybutene, red 6 lake¹, theobroma cacao (cocoa) seed butter, titanium dioxide

¹ may contain these ingredients

PRINCIPAL DISPLAY PANEL - Kit Carton

VALUE

PACK

Blistex[®]

LIP PROTECTANT/SUNSCREEN

Mint

Berry

Classic

MEDICATED

LIP BALM

Smooth, Easy-Gliding
Protection

Seals In Moisture
To Soothe & Prevent
Dry Lips

SPF 15

3 Balm

VALUE

PACK

3 Sticks Net Wt. 0.15 oz. (4.25 g) Ea.

VALUE PACK

Blistex

LIP PROTECTANT/SUNSCREEN



Mint



Berry



Classic

MEDICATED LIP BALM

Smooth, Easy-Gliding Protection

Seals In Moisture To Soothe & Prevent Dry Lips

SPF 15

3 Sticks Net Wt. 0.15 oz. (4.25 g) Ea.

3 Balm VALUE PACK



SATISFACTION GUARANTEED
Blistex

C030159



propylparaben, menthyl salicylate, mineral oil, cokerite, paraffin, petrolatum, phenoxyethanol, polybutene, red 6 lake, theobroma cacao (cocoa) seed butter, titanium dioxide
*may contain these ingredients

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- 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



BLISTEX MEDICATED LIP BALM VARIETY PACK (BLISTEX MEDICATED BERRY LIP BALM, BLISTEX MEDICATED LIP BALM, BLISTEX MEDICATED MINT LIP BALM)
 dimethicone, octinoxate, and octisalate kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 157-9908

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 157-9908-1	1 in 1 CARTON	02/03/2020	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 CYLINDER	4.25 g
Part 2	1 CYLINDER	4.25 g
Part 3	1 CYLINDER	4.25 g

Part 1 of 3

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
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.6 g in 100 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
CERESIN (UNII: Q1LS2UJO3A)	
CANDELILLA WAX (UNII: WL0328HX19)	
LANOLIN OIL (UNII: OVV5IJ58F)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LANOLIN (UNII: 7EV65EAW6H)	
POLYBUTENE (1400 MW) (UNII: 1NA5A09GH7)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PARAFFIN (UNII: I9O0E3H2ZE)	
COCOA BUTTER (UNII: 512OYT1CRR)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.,.ALPHA.-DIBROMO-D-CAMPHOR (UNII: F89Z8SAG3O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 6 (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 FINAL	part347	02/03/2020	

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
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.6 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
CERESIN (UNII: Q1LS2UJO3A)	
CANDELILLA WAX (UNII: WL0328HX19)	
LANOLIN OIL (UNII: OVV5IJJ58F)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LANOLIN (UNII: 7EV65EAW6H)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PARAFFIN (UNII: I9O0E3H2ZE)	
COCOA BUTTER (UNII: 512OYT1CRR)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.,.ALPHA.-DIBROMO-D-CAMPHOR (UNII: F89Z8SAG3O)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 6 (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 3 of 3**BLISTEX MEDICATED MINT LIP BALM**

dimethicone, octinoxate, and octisalate ointment

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.6 g in 100 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
CERESIN (UNII: Q1LS2UJO3A)	
CANDELILLA WAX (UNII: WL0328HX19)	
LANOLIN OIL (UNII: OVV5IJ58F)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LANOLIN (UNII: 7EV65EAW6H)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PARAFFIN (UNII: I9O0E3H2ZE)	
COCOA BUTTER (UNII: 512OYT1CRR)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.,.ALPHA.-DIBROMO-D-CAMPHOR (UNII: F89Z8SAG3O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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 final	part347	02/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	02/03/2020	

Labeler - Blistex Inc (005126354)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc		005126354	MANUFACTURE(10 157-9908)

Revised: 2/2020

Blistex Inc