

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

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 Lip Ointment)

MEDICATED BERRY 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, 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

<i>Active ingredients</i>	<i>Purpose</i>
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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, methyl salicylate, mineral oil, ozokerite, paraffin, petrolatum, phenoxyethanol, polybutene, red 6 lake, theobroma cacao (cocoa) seed butter, titanium dioxide

MEDICATED LIP OINTMENT

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
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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



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

Drug Facts	Active ingredients Purpose Dimethicone 2.0% (w/w) Lip protectant Octinoxate 6.6% (w/w) Sunscreen Octisalate 4.4% (w/w) Sunscreen
Uses	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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
Drug Facts (continued)	Other information <ul style="list-style-type: none"> 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



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	Active ingredients Purpose 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	<ul style="list-style-type: none"> 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:	<ul style="list-style-type: none"> deep or puncture wounds animal bites serious burns
When using this product:	<ul style="list-style-type: none"> do not get into eyes do not apply over large areas of the body or bandage
Stop use and ask a doctor if:	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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
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.

Drug Facts	
Active ingredients	Purpose
Dimethicone 2.0% (w/w) Lip protectant Octinoxate 6.6% (w/w) Sunscreen Octisalate 4.4% (w/w)	Lip protectant Sunscreen
Uses	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> 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 	

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, 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)

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 157-99 10
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 157-99 10-1	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 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
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: 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 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
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	1.1 g in 100 g
Camphor (Synthetic) (UNII: 5TJD82A1ET) (Camphor (Synthetic) - UNII:5TJD82A1ET)	Camphor (Synthetic)	0.5 g in 100 g
Menthol, Unspecified Form (UNII: L7T10EIP3A) (Menthol, Unspecified Form - UNII:L7T10EIP3A)	Menthol, Unspecified Form	0.625 g in 100 g
Phenol (UNII: 339NCG44TV) (Phenol - UNII:339NCG44TV)	Phenol	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
PETROLATUM (UNII: 4T6H12BN9U)	
LANOLIN (UNII: 7EV65EAW6H)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
PARAFFIN (UNII: I9O0E3H2ZE)	
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALLANTOIN (UNII: 344S277G0Z)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
PALMITIC ACID (UNII: 2V16EO95H1)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	
LAURIC ACID (UNII: 1160N9NU9U)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
OLEIC ACID (UNII: 2UMI9U37CP)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
POTASSIUM HYDROXIDE (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 not final	part348	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(10 157-9910)

Revised: 2/2020

Blistex Inc