

BLISTEX FIVE STAR LIP PROTECTION BROAD SPECTRUM- homosalate, octisalate, avobenzone, and dimethicone stick

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®
Five Star Lip Protection® Broad Spectrum**

Drug Facts

Active ingredients	Purpose
Avobenzone 3.0% (w/w)	Sunscreen
Dimethicone 2.0% (w/w)	Lip Protectant
Homosalate 15.0 % (w/w)	Sunscreen
Octisalate 5.0 % (w/w)	Sunscreen

Uses

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

For external use only

Do not use on damaged or broken skin

Stop use and ask a doctor if rash occurs

When using this product keep out of eyes. Rinse with water to remove.

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 6 months of age: Ask a doctor
- **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 a 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 sleeve shirts, pants, hats, and sunglasses

Other information

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

Inactive ingredients

bis-diglyceryl polyacyladipate-2, bis-stearyl dimethicone, butyloctyl salicylate, C12-15 alkyl benzoate, calendula officinalis extract, caprylic/capric triglyceride, carthamus tinctorius (safflower) seed oil, cetyl dimethicone, citric acid, euphorbia cerifera (candelilla) wax, flavor, microcrystalline wax, myristyl myristate, octyldodecanol, oryzanol, ozokerite, panthenol, phenoxyethanol, sorbic acid, stearyl behenate, sucralose, tetrahexyldecyl ascorbate, tocopheryl acetate, triticum vulgare (wheat) germ oil

PRINCIPAL DISPLAY PANEL - 4.25 g Cylinder Blister Pack

The Ultimate
Daily Protection
For Lips

Blistex®

FIVE STAR
Lip Protection®

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10157-1171
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	15 g in 100 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	5 g in 100 g
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	3 g in 100 g
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
CERESIN (UNII: Q1LS2UJO3A)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
STEARYL BEHENATE (UNII: A68S9UI39D)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)	
CANDELILLA WAX (UNII: WL0328HX19)	
ORYZANOL (UNII: SST9XCL51M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
WHEAT GERM OIL (UNII: 14C97E680P)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SORBIC ACID (UNII: X045WJ989B)	
PANTHENOL (UNII: WV9CM0067Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10157-1171-1	1 in 1 BLISTER PACK	08/22/2020	
1		4.25 g in 1 CYLINDER; Type 0: Not a Combination Product		
2	NDC:10157-1171-2	2 in 1 BLISTER PACK	08/22/2020	
2		4.25 g in 1 CYLINDER; Type 0: Not a Combination Product		
3	NDC:10157-1171-3	3 in 1 BLISTER PACK	08/22/2020	
3		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	part352	08/22/2020	

Labeler - Blistex Inc. (005126354)**Establishment**

Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	MANUFACTURE(10157-1171)

Revised: 8/2020

Blistex Inc.