

BLISTEX FIVE STAR- lip protection 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.

DRUG FACTS

Petrolatum

Hemosalate

Octinoxate

Oxybenzone

Octisalate

SKIN PROTECTANT/ SUNSCREEN

- Temporarily protects and helps relieve chapped or cracked lips
- Helps protect lips from the drying effects of wind, cold weather
- Helps prevent sunburn

FOR EXTERNAL USE ONLY

- Do not use on * deep puncture wounds* animal bites* serious burns
- Stop use if skin rash occurs
- Adults and children 2 years of age and older: apply liberally to affected area not more than 3 to 4 times daily.
- Children under 2 years of age : consult a doctor.

BLISTEX

FIVE STAR

LIP PROTECTION

- Holds in moisture in **Dry** air
- Soothes **cold** chapped lips
- Rehydrates **heat** stressed lips
- Forms a **wind** resistant moisture shield
- UVA/UVB **sun** protection

NET WT. .15oz. (4.25g) SPF

BLISTEX FIVE STAR

lip protection stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 157-9825
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	30.1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	9.6 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5.0 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5.0 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 157-9825-1	1 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/01/2010	

Labeler - Blistex Inc (005126354)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc		005126354	manufacture

Revised: 1/2010

Blistex Inc