

**TOP SECRETS BB PRIMER SPF 25- octinoxate cream
BPS 60**

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.

Top Secrets BB Cream Primer SPF 25

Drug Facts

Active ingredients

Octinoxate 7.49%

Purpose

Sunscreen

Use

- 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

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

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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-sleeved shirts, pants, hats, and sunglasses
- 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

water, glycerin, propylene glycol, cyclohexasiloxane, octyldodecanol, stearic acid, potassium cetyl phosphate, palmitic acid, PEG-100 stearate, glyceryl stearate, phenoxyethanol, triethanolamine, cetyl alcohol, talc, dimethicone, silica, fragrance, perfluorooctyl triethoxysilane, methylparaben, caprylyl glycol, carbomer, ophiopogon japonicus root extract, ethylparaben, aluminum hydroxide, capryloyl salicylic acid, xanthan gum, pentylene glycol, hydrolyzed soy protein, myristic acid, disodium EDTA, adenosine, alumina, fluorophlogopite, hydrolyzed linseed extract, benzyl alcohol, ascorbyl glucoside, BHT, ethylhexylglycerin, sodium benzoate, isoeugenol, acetyl tetrapeptide-9, rosa centifolia flower extract; may contain: titanium dioxide, iron oxides, carmine.

Package Labeling:



TOP SECRETS BB PRIMER SPF 25

octinoxate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70581-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	74.9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PALMITIC ACID (UNII: 2V16EO95HI)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TROLAMINE (UNII: 9O3K93S3TK)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PERFLUORO OCTYL TRIETHOXY SILANE (UNII: 814P46684U)	
METHYL PARABEN (UNII: A218C7H9T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
OPHIPOGON JAPONICUS ROOT (UNII: 90PS6JV9GZ)	
ETHYL PARABEN (UNII: 14255EXE39)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CAPRYLOYL SALICYLIC ACID (UNII: 5F7PJF6AA4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	
MYRISTIC ACID (UNII: 01BV7S25AW)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ADENOSINE (UNII: K72T3FS567)	
ALUMINUM OXIDE (UNII: LM26O6933)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ISOEUGENOL (UNII: 5M0MWY797U)	
ACETYL TETRAPEPTIDE-9 (UNII: VMO8OOD3V0)	
ROSA CENTIFOLIA FLOWER (UNII: CS4TE8FF7O)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70581-015-00	1 in 1 BOX	12/26/2017	
1		40 mL 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	part352	12/26/2017	

Labeler - BPS 60 (272259304)

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BPS 60