ALL HOURS PRIMER SPF 18- 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.

All Hours Primer SPF 18

Drug Facts

Active ingredient

Octinoxate 6.5%

Purpose

Sunscreen

Uses

- 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

Flammable until dry. Avoid fire, flame and heat during application.

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:

- shake well before 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

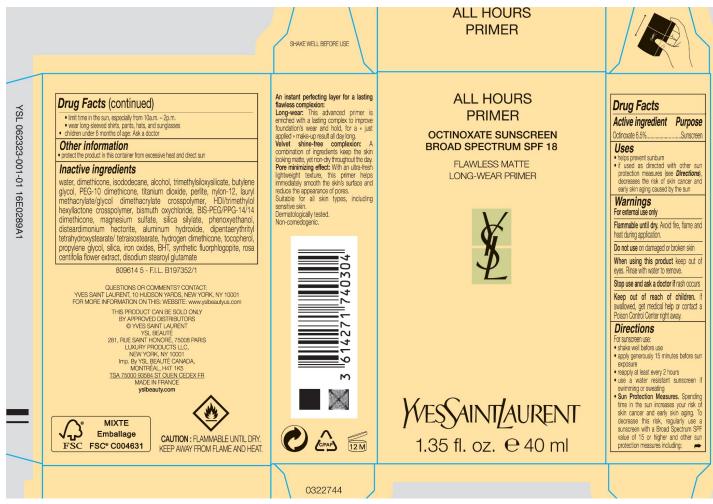
Other information

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

Inactive ingredients

water, dimethicone, isododecane, alcohol, trimethylsiloxysilicate, butylene glycol, PEG-10 dimethicone, titanium dioxide, perlite, nylon-12, lauryl methacrylate/glycol dimethacrylate crosspolymer, HDI/trimethylol hexyllactone crosspolymer, bismuth oxychloride, BIS-PEG/PPG-14/14 dimethicone, magnesium sulfate, silica silylate, phenoxyethanol, disteardimonium hectorite, aluminum hydroxide, dipentaerythrityl tetrahydroxystearate/tetraisostearate, hydrogen dimethicone, tocopherol, propylene glycol, silica, iron oxides, BHT, synthetic fluorphlogopite, rosa centifolia flower extract, disodium stearoyl glutamate

Package Labeling:



ALL HOURS PRIMER SPF 18

octinoxate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70581-018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	65 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
ISODODECANE (UNII: A8289P68Y2)		
ALCOHOL (UNII: 3K9958V90M)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
PEG-10 DIMETHICO NE (600 CST) (UNII: 8 PR7V1SVM0)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
PERLITE (UNII: 0 SG10 1ZGK9)		
NYLON-12 (UNII: 446 U8J0 75B)		
LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EX0F4CZ66H)		
HEXAMETHYLENE DIISO CYANATE/TRIMETHYLO L HEXYLLACTO NE CROSSPOLYMER (UNII: WB5K9 Y35Y9)		
BISMUTH O XYCHLO RIDE (UNII: 4ZR792I587)		
BIS-PEG/PPG-14/14 DIMETHICO NE (UNII: X2I70 H0 QJE)		
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)		
PHENO XYETHANO L (UNII: HIE49 2ZZ3T)		
DISTEARDIMO NIUM HECTO RITE (UNII: X687XDK09L)		
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)		
DIPENTAERYTHRITYL TETRAHYDRO XYSTEARATE/TETRAISO STEARATE (UNII: 230 K0 8 23CE)		
TOCOPHEROL (UNII: R0ZB2556P8)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		
ROSA CENTIFOLIA FLOWER (UNII: CS4TE8FF7O)		
DISO DIUM STEARO YL GLUTAMATE (UNII: 45ASM2L11M)		

]	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70581-018-00	1 in 1 CARTON	12/25/2017	
1		40 mL in 1 BOTTLE; 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	12/25/2017	

Labeler - BPS 60 (272259304)

Revised: 12/2019 BPS 60