PREVAGE ANTI AGING SPF 30- octisalate, octinoxate, oxybenzone, avobenzone, octocrylene, lotion
Revlon

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.

Prevage Anti-aging moisture lotion SPF 30

ACTIVE INGREDIENTS

OCTINOXATE, 7.5 %

OCTISALATE, 5.0 %

OXYBENZONE, 5.0 %

OCTOCRYLENE, 2.2 %

AVOBENZONE, 2.0 %

Inactive Ingredients

WATER/AQUA/EAU, GLYCERIN, DIMETHICONE, CETEARYL ALCOHOL, PROPYLENE GLYCOL, C12-15 ALKYL BENZOATE, PEG-40 HYDROGENATED CASTOR OIL, POTASSIUM CETYL PHOSPHATE, GLYCERYL POLYACRYLATE, GLYCERYL STEARATE, BUTYROSPERMUM PARKII (SHEA) BUTTER, CARBOMER, CYCLOHEXASILOXANE, CYCLOPENTASILOXANE, ERGOTHIONEINE, HYDROGENATED PALM GLYCERIDES, HYDROXYDECYL UBIQUINOYL DIPALMITOYL GLYCERATE, MICA, PARFUM/FRAGRANCE, POLYQUATERNIUM-51, SODIUM HYALURONATE, SODIUM HYDROXIDE, SODIUM PCA, TREHALOSE, UREA, BHT, ALPHA-ISOMETHYL IONONE, LINALOOL, BENZOIC ACID, CHLORPHENESIN, METHYLPARABEN, PHENOXYETHANOL, IRON OXIDES, YELLOW (CI 77492), RED 4 (CI 14700), TITANIUM DIOXIDE (CI 77891), YELLOW 5 (CI 19140).

Purpose

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 using and ask a docotr is rash occurs.

Keep out of reach of children. if product is swallowed, get medical help or contact a Poison Control Center right away.

Directions For Sunscreen Use:

Apply liberally 15 minutes before sun exposure

Replly:

- at least every 2 hours

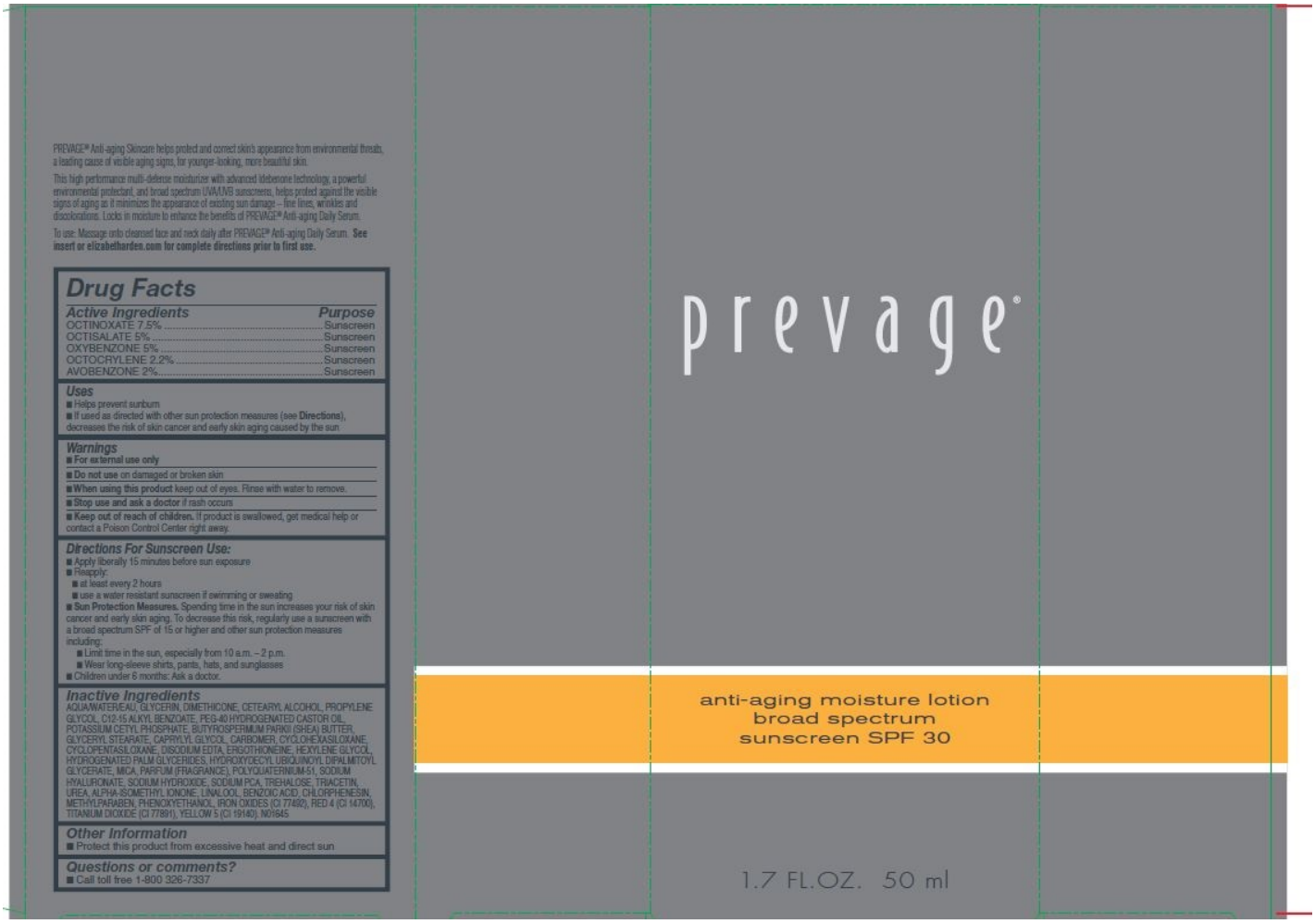
- use a water resistant sunscreen if swimming or sweating

Sun Protection measures. Spending time in the sun increases your risk od skin cancer and warly skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF 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.

- Children under 6 months: Ask a doctor.



PREVAGE ANTI AGING SPF 30
octisalate, octinoxate, oxybenzone, avobenzone, octocrylene, lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10967-686
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.2 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARBOMER 1342 (UNII: 809Y72KV36)	
DIMETHICONE 1000 (UNII: MCU2324216)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SHEA BUTTER (UNII: K49155WL9Y)	
HYDROXYDECYL UBIQUINOYL DIPALMITOYL GLYCERATE (UNII: OV1BT2N8RC)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TREHALOSE (UNII: B8WCK70T7I)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 4:1) (UNII: X8Q92E1CPM)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
ACRYLIC ACID (UNII: J94PBK7X8S)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	

ERGOTHIONEINE (UNII: BDZ3DQM98W)	
UREA (UNII: 8W8T17847W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
2-(4-(DIETHYLAMINO)-2-HYDROXYBENZOYL)BENZOIC ACID (UNII: X4K32L28QB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10967-686-17	50 mL in 1 TUBE; Type 0: Not a Combination Product	01/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/02/2020	

Labeler - Revlon (788820165)

Establishment

Name	Address	ID/FEI	Business Operations
Englewood Lab. INC.		080987545	manufacture(10967-686)

Revised: 2/2022 Revlon