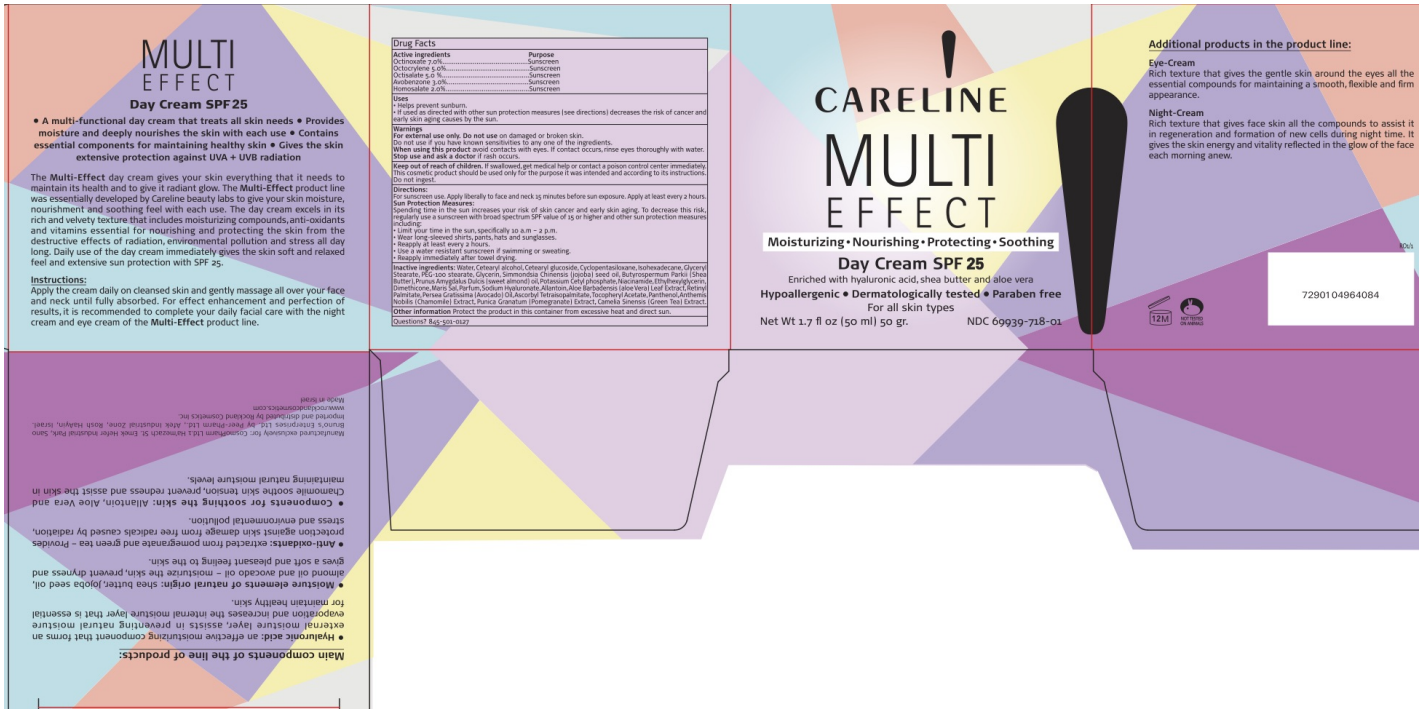
MULTI EFFECT DAY CREAM SPF 25- octinoxate, octocrylene, octisalate, avobenzone, homosalate cream
Sano International Ltd.

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.

Multi Effect Day Cream SPF 25



Octinoxate 7%

Octocrylene 5%

Octisalate 5%

Avobenzone 3%

Homosalate 2%

Keep out of reach of children.

Provides SPF 25 protection

To Use: Smooth onto face.
For Sunscreen Use: Apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours. 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 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.

Smooth on to face.

MULTI EFFECT DAY CREAM SPF 25

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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69435-1701
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
JOJOBA OIL (UNII: 724GKU717M)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALMOND OIL (UNII: 66YXD4DKO9)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALLANTOIN (UNII: 344S277G0Z)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
SHEA BUTTER (UNII: K49155WL9Y)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
NIACINAMIDE (UNII: 25X51I8RD4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SEA SALT (UNII: 87GE52P74G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WV9CM0O67Z)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
WATER (UNII: 059QF0KO0R)	
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:69435-1701-1	50 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/29/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/23/2016	

Labeler - Sano International Ltd. (514678390)

Registrant - Peer Pharma Ltd. (514678390)

Establishment

Name	Address	ID/FEI	Business Operations
Peer Pharma Ltd.		514678390	manufacture(69435-1701)

Establishment

Name	Address	ID/FEI	Business Operations
Sano International Ltd.		600395487	label(69435-1701)

Revised: 11/2017 Sano International Ltd.