

MARY KAY TIMEWISE REPAIR VOLU-FIRM DAY CREAM BROAD SPECTRUM SPF 30- avobenzone, homosalate, octisalate, octocrylene, oxybenzone cream
Mary Kay 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.

Mary Kay TimeWise Repair VoluFirm Day Cream SPF 30 (2018 update)
Drug Facts

Active Ingredients

Avobenzone 3%

Homosalate 9%

Octisalate 4.5%

Octocrylene 4%

Oxybenzone 4.5%

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

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- use a water-resistant sunscreen if swimming or sweating
- 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
 - children under 6 months: Ask a doctor

Inactive ingredients

water, butylene glycol, glycerin, cetearyl alcohol, behenyl alcohol, dicaprylyl carbonate, ammonium acryloyldimethyltaurate/VP copolymer, dimethicone, ceteareth-25, pentyleneglycol, tripeptide-1, tocopheryl acetate, hexylresorcinol, sodium PCA, centella asiatica meristem cell culture, silybum marianum fruit extract, cestrum latifolium leaf extract, calcium ketogluconate, 4-t-butylcyclohexanol, disodium ethylene dicocamide PEG-15 disulfate, bisabolol, xanthan gum, methyl dihydrojasmonate, ethylene brassylate, ethyl linalool, disodium EDTA, trimethylbenzenepropanol, isobutyl methyl tetrahydropyranol, gamma-undecalactone, phenylisohexanol, sodium benzoate, tetradecyl aminobutyroylvalylaminobutyric urea trifluoroacetate, silica, triethanolamine, citric acid, propanediol, caprylyl glycol, decylene glycol, hydroxypropyl cyclodextrin, phenoxyethanol, hexylene glycol, ethylhexylglycerin, 1,2-hexanediol, magnesium chloride, iodopropynyl butylcarbamate

Other information

- protect this product from excessive heat and direct sun. Store above 32° F / 0° C.

Questions or comments?

Call toll free 1-800-627-9529

Principal Display Panel - 48 g carton

Mary Kay

timewise repair

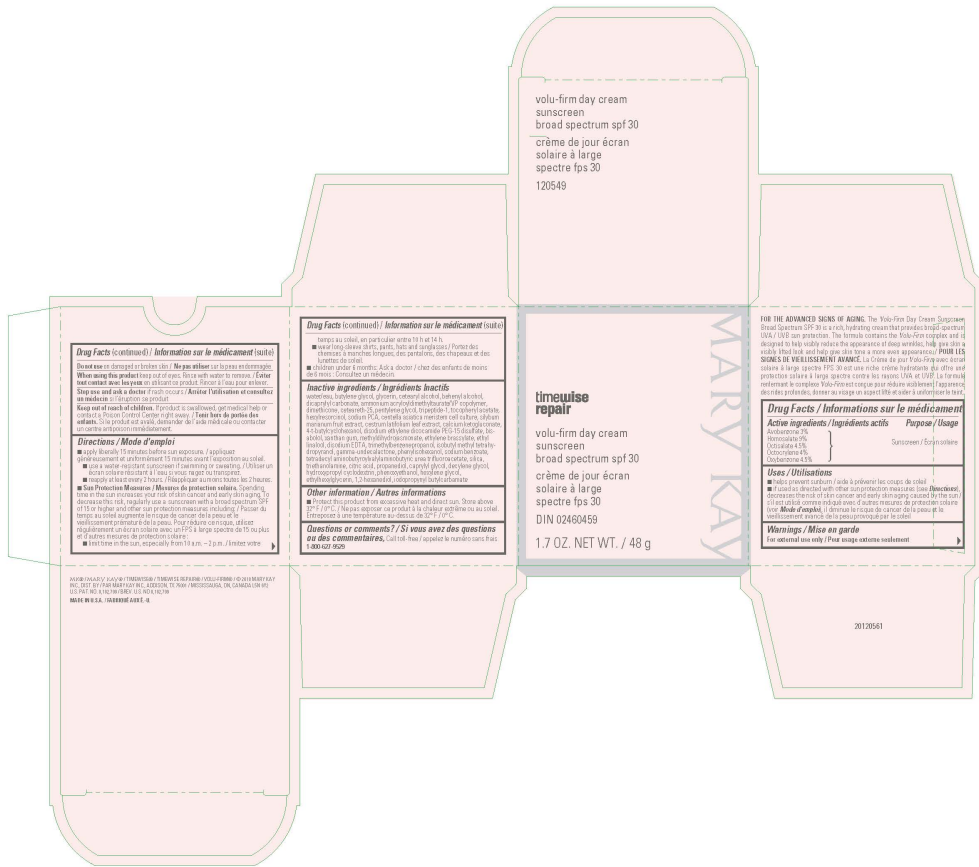
volu-firm day cream

sunscreen

broad spectrum

spf 30

1.7 OZ. NET WT. / 48 g



MARY KAY TIMEWISE REPAIR VOLU-FIRM DAY CREAM BROAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate, octocrylene, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51531-0549
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	3 g in 100 g
HOMOSALATE (UNII: V065SV4M95S) (HOMOSALATE - UNII:V065SV4M95S)	HOMOSALATE	9 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZ ONE - UNII:95OOS7VE0Y)	OXYBENZ ONE	4.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DOCOSANOL (UNII: 9G1OE216XY)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
AMMONIUM ACRYLOYLDIMETHYLTAUROATE/VP COPOLYMER (UNII: W59H9296ZG)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETEARETH-25 (UNII: 8FA93U5T67)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
METHYL DIHYDROJASMONATE (SYNTHETIC) (UNII: 3GW44CIE3Y)	
DISODIUM ETHYLENE DICOCAMIDE PEG-15 DISULFATE (UNII: QI9A6U005W)	
CALCIUM 2-KETOGLUCONATE (UNII: 8K5SM7SI6Y)	
HEXYLRESORCINOL (UNII: R9QTB5E82N)	
4-TERT-BUTYLCYCLOHEXANOL (UNII: K0H1405S9C)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYL LINALOOL (UNII: SF2JS9GF5T)	
TROLAMINE (UNII: 9O3K93S3TK)	
LEVOMENOL (UNII: 24WE03BX2T)	
DECYLENE GLYCOL (UNII: S57M60MI88)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYDROXYPROPYL .ALPHA.-CYCLODEXTRIN (UNII: ZFR0T80O4Y)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
TRIMETHYLBENZENEPROPANOL (UNII: 7S411YY2VY)	
2-ISOBUTYL-4-METHYLTETRAHYDROPYRAN-4-OL (UNII: VK5ZHH2T3F)	
MILK THISTLE (UNII: U946SH95EE)	
.GAMMA.-UNDECALACTONE (UNII: QB1T0AG2YL)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PHENYLISOHEXANOL (UNII: M56178H183)	
PROPANEDIOL (UNII: 5965N8W85T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
CESTRUM LATIFOLIUM LEAF (UNII: O2618B6E88)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TETRADECYL AMINOBUTYROYLVALYLAMINOBUTYRIC UREA TRIFLUOROACETATE (UNII: 0UBP26S1LG)	
PREZATIDE (UNII: 39TG2H631E)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51531-0549-7	1 in 1 CARTON	05/16/2019	
		48 in 1 UAB; Type O; Net a Combination		

1		48 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:51531-0549-3	9 g in 1 TUBE; Type 0: Not a Combination Product	05/16/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	M020		05/16/2019	

Labeler - Mary Kay Inc. (049994452)

Establishment			
Name	Address	ID/FEI	Business Operations
Englewood Lab Inc.		172198223	manufacture(51531-0549)

Establishment			
Name	Address	ID/FEI	Business Operations
Mary Kay Inc.		103978839	manufacture(51531-0549)