

BLACK RADIANCE TRUE COMPLEXION BB CREAM SPF 15- homosalate, octisalate, octocrylene cream

Markwins Beauty Products 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.

Drug Facts

Drug Facts

PO#	
ITEM	8917-8921
要求打样确认	<input type="checkbox"/>
语种	<input type="checkbox"/>
物料编号	Q4批准



BACK LABEL GRAPHICS:
GREY IS 80 PERCENT BLACK



DIECUT: CYAN

红色部分代表透明区域

SIZE: 3.4"

font sizes:
9 pt
subheaders: 8 pt
body: 6 pt

8917 (café)
Cover: Drug Facts, Active Ingredients Purpose, Homosalate 4%, Octisalate 2%, Octocrylene 3%, Sunscreen, Use, Warnings, Skin Cancer/Skin Aging Alerts, Directions, Inactive Ingredients.
Flip Back of Cover: Drug Facts (continued), Do not use on damaged or broken skin, Directions, Inactive Ingredients.
Second sheet of label: Drug Facts (continued), Active Ingredients Purpose, Homosalate 4%, Octisalate 2%, Octocrylene 3%, Sunscreen, Use, Warnings, Skin Cancer/Skin Aging Alerts, Directions, Inactive Ingredients, Other Information.

8918 (chocolate)
Cover: Drug Facts, Active Ingredients Purpose, Homosalate 4%, Octisalate 2%, Octocrylene 3%, Sunscreen, Use, Warnings, Skin Cancer/Skin Aging Alerts, Directions, Inactive Ingredients.
Flip Back of Cover: Drug Facts (continued), Do not use on damaged or broken skin, Directions, Inactive Ingredients.
Second sheet of label: Drug Facts (continued), Active Ingredients Purpose, Homosalate 4%, Octisalate 2%, Octocrylene 3%, Sunscreen, Use, Warnings, Skin Cancer/Skin Aging Alerts, Directions, Inactive Ingredients, Other Information.

8919 (honey amber)
Cover: Drug Facts, Active Ingredients Purpose, Homosalate 4%, Octisalate 2%, Octocrylene 3%, Sunscreen, Use, Warnings, Skin Cancer/Skin Aging Alerts, Directions, Inactive Ingredients.
Flip Back of Cover: Drug Facts (continued), Do not use on damaged or broken skin, Directions, Inactive Ingredients.
Second sheet of label: Drug Facts (continued), Active Ingredients Purpose, Homosalate 4%, Octisalate 2%, Octocrylene 3%, Sunscreen, Use, Warnings, Skin Cancer/Skin Aging Alerts, Directions, Inactive Ingredients, Other Information.

8920 (brown sugar)
Cover: Drug Facts, Active Ingredients Purpose, Homosalate 4%, Octisalate 2%, Octocrylene 3%, Sunscreen, Use, Warnings, Skin Cancer/Skin Aging Alerts, Directions, Inactive Ingredients.
Flip Back of Cover: Drug Facts (continued), Do not use on damaged or broken skin, Directions, Inactive Ingredients.
Second sheet of label: Drug Facts (continued), Active Ingredients Purpose, Homosalate 4%, Octisalate 2%, Octocrylene 3%, Sunscreen, Use, Warnings, Skin Cancer/Skin Aging Alerts, Directions, Inactive Ingredients, Other Information.

BLACK RADIANCE TRUE COMPLEXION BB CREAM SPF 15

homosalate, octisalate, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12027-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	4 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	2 g in 100 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
PROPYLENE GLYCOL STEARATE (UNII: MZMI1680W0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL 1-LAURATE (UNII: M4AW13H75T)	
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ULTRAMARINE BLUE (UNII: B9WR998B1)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 3) (UNII: G300307ZXP)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12027-106-12	29.6 mL in 1 TUBE; Type 0: Not a Combination Product	09/13/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final

part352

09/13/2013

Labeler - Markwins Beauty Products Inc. (135407760)

Revised: 1/2019

Markwins Beauty Products Inc.