

PROTECTINT 20C- homosalate, octisalate, zinc oxide cream
PROTECTINT 26W- homosalate, octisalate, zinc oxide cream
PROTECTINT 32N- homosalate, octisalate, zinc oxide cream
PROTECTINT 34C- homosalate, octisalate, zinc oxide cream
PROTECTINT 58W- homosalate, octisalate, zinc oxide cream
PROTECTINT 10N- homosalate, octisalate, zinc oxide cream
PROTECTINT 24N- homosalate, octisalate, zinc oxide cream
PROTECTINT 22W- homosalate, octisalate, zinc oxide cream
PROTECTINT 30W- homosalate, octisalate, zinc oxide cream
PROTECTINT 46N- homosalate, octisalate, zinc oxide cream
PROTECTINT 42C- homosalate, octisalate, zinc oxide cream
PROTECTINT 52N- homosalate, octisalate, zinc oxide cream
PROTECTINT 14N- homosalate, octisalate, zinc oxide cream
PROTECTINT 40W- homosalate, octisalate, zinc oxide cream
MANA PRODUCTS, INC.

Protec(tint) SPF 50

Active Ingredients: Zinc Oxide 13.58%, Homosalate 7.0%, Octisalate 5.0%

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

Keep out of reach of children. If product is swallowed, get medical help, or contact a poison control center right away.

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

Directions

Apply generously and evenly 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: Ask a doctor

Inactive Ingredients: Aqua/Water/Eau, Isononyl Isononanoate, Butyloctyl Salicylate, Propanediol, Silica, Glycerin, 1,2-Hexanediol, Lecithin, Coco-Caprylate/Caprates, Cetearyl Alcohol, Lauryl Glucoside, Polyglyceryl-2 Dipolyhydroxystearate, Ammonium Acryloyldimethyltaurate/VP Copolymer, Ectoin, Coco-Glucoside, Polyhydroxystearic acid,

Citric Acid, Triethoxycaprylylsilane, Morinda Citrifolia Extract, Xanthan Gum, Sodium Phytate, Bentonite, Sodium Hyaluronate, Tocopherol

Protec(tint)

Daily SPF Tint

SPF 50

Broad Spectrum Tinted

Sunscreen SPF 50

1.18 fl. oz. / 35 ml.

PROTEC(TINT) DAILY SPF TINT SPF 50 is an effortless, blendable skin tint with powerful sun protection, a barely-there feel & light coverage for a visibly even, smooth complexion with a natural finish.

Drug Facts	
Active Ingredients	Purpose
Zinc Oxide 13.58%, Homosalate 7.0%, Octisalate 5.0%	Sunscreens
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 generously and evenly 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: Ask a doctor	
Inactive Ingredients Aqua/Water/Eau, Isononyl Isononanoate, Butyloctyl Salicylate, Propanediol, Silica, Glycerin, 1,2-Hexanediol, Lecithin, Coco-Caprylate/Caprate, Cetearyl Alcohol, Lauryl Glucoside, Polyglyceryl-2 Dipolyhydroxystearate, Ammonium Acryloyldimethyltaurate/VP Copolymer, Ectoin, Coco-Glucoside, Polyhydroxystearic acid, Citric Acid, Triethoxycaprylylsilane, Morinda Citrifolia Extract, Xanthan Gum, Sodium Phytate, Bentonite, Sodium Hyaluronate, Tocopherol. May Contain (+/-): Titanium Dioxide (CI 77891), Iron Oxides (CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499)	
Other Information Protect the product in this container from excessive heat and direct sun	
Questions or comments? Contact our Sun Specialists 877-564-7330	

Supergoop!

PROTEC(TINT)

DAILY SPF TINT



Broad Spectrum Tinted
Sunscreen SPF 50 PA++++

1.18 fl. oz. / 35 ml.

**Dermatologist-Tested • Safe For All Skin
Types • Non-Irritating • No Synthetic
Fragrance • Vegan**

Active Ingredients	Purpose
Zinc Oxide (13.58%), Homosalate (7.0%), Octisalate (5.0%).....	Sunscreens

Directions: Apply generously and evenly 15 minutes before sun exposure. Blend onto skin with fingertips and build to desired coverage. Reapply at least every 2 hours.

Contact our Sun Specialists
for Questions: 877.564.7330

supergoop.com
Distributed by Supergoop, LLC
San Antonio, TX 78215



SHADE LABELS

10N

14N

20C

22W

24N

26W

30W

32N

34C

40W

42C

46N

52N

58W

PROTECTINT 20C

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-906
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
COCO GLUCOSIDE (UNII: ICS790225B)	
WATER (UNII: 059QF0K00R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BENTONITE (UNII: A3N5ZCN45C)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ECTOINE (UNII: 7GXZ3858RY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONI FRUIT (UNII: 7829X3G2X5)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	

Product Characteristics

Color	white (20C)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-906-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-906-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 26W

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-907
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONI FRUIT (UNII: 7829X3G2X5)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
COCO GLUCOSIDE (UNII: ICS790225B)	
WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BENTONITE (UNII: A3N5ZCN45C)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ECTOINE (UNII: 7GXZ3858RY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	white (26W)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-907-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-907-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 32N

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-908
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
GLYCERIN (UNII: PDC6A3C0OX)
NONI FRUIT (UNII: 7829X3G2X5)
PHYTATE SODIUM (UNII: 88496G1ERL)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
XANTHAN GUM (UNII: TTV12P4NEE)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
PROPANEDIOL (UNII: 5965N8W85T)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)
COCO GLUCOSIDE (UNII: ICS790225B)
WATER (UNII: 059QF0KO0R)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
BENTONITE (UNII: A3N5ZCN45C)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ECTOINE (UNII: 7GXZ3858RY)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

Product Characteristics

Color	brown (32N)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-908-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-908-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 34C

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-909
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONI FRUIT (UNII: 7829X3G2X5)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
COCO GLUCOSIDE (UNII: ICS790225B)	
WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BENTONITE (UNII: A3N5ZCN45C)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ECTOINE (UNII: 7GXZ3858RY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	brown (34C)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-909-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-909-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 58W

homosalate, octisalate, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-910
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONI FRUIT (UNII: 7829X3G2X5)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
XANTHAN GUM (UNII: TTV12P4NEE)	

HYALURONATE SODIUM (UNII: YSE9PPT4TH)
PROPANEDIOL (UNII: 5965N8W85T)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)
COCO GLUCOSIDE (UNII: ICS790225B)
WATER (UNII: 059QF0KO0R)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
BENTONITE (UNII: A3N5ZCN45C)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ECTOINE (UNII: 7GXZ3858RY)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

Product Characteristics

Color	brown (58W)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-910-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-910-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 10N

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-911
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONI FRUIT (UNII: 7829X3G2X5)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
COCO GLUCOSIDE (UNII: ICS790225B)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BENTONITE (UNII: A3N5ZCN45C)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ECTOINE (UNII: 7GXZ3858RY)	

Product Characteristics

Color	white (10N)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:59735-911-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-911-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 24N

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-912
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONI FRUIT (UNII: 7829X3G2X5)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
COCO GLUCOSIDE (UNII: ICS790225B)	

WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BENTONITE (UNII: A3N5ZCN45C)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ECTOINE (UNII: 7GXZ3858RY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	white (24N)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-912-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-912-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 22W

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-913
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONI FRUIT (UNII: 7829X3G2X5)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
COCO GLUCOSIDE (UNII: ICS790225B)	
WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
LECITHIN, SUNFLOWER (UNII: 834K0W0S5G)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BENTONITE (UNII: A3N5ZCN45C)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ECTOINE (UNII: 7GXZ3858RY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	white (22W)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-913-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-913-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 30W

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-914
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONI FRUIT (UNII: 7829X3G2X5)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
COCO GLUCOSIDE (UNII: ICS790225B)	
WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BENTONITE (UNII: A3N5ZCN45C)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ECTOINE (UNII: 7GXZ3858RY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	brown (30W)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-914-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-914-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 46N

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-915
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
GLYCERIN (UNII: PDC6A3C0OX)
NONI FRUIT (UNII: 7829X3G2X5)
PHYTATE SODIUM (UNII: 88496G1ERL)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
XANTHAN GUM (UNII: TTV12P4NEE)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
PROPANEDIOL (UNII: 5965N8W85T)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER (UNII: W59H9296ZG)
COCO GLUCOSIDE (UNII: ICS790225B)
WATER (UNII: 059QF0KO0R)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
BENTONITE (UNII: A3N5ZCN45C)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ECTOINE (UNII: 7GXZ3858RY)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

Product Characteristics

Color	brown (46N)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-915-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-915-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 42C

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-916
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONI FRUIT (UNII: 7829X3G2X5)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
COCO GLUCOSIDE (UNII: ICS790225B)	
WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BENTONITE (UNII: A3N5ZCN45C)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ECTOINE (UNII: 7GXZ3858RY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	brown (42C)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-916-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-916-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 52N

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-917
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONI FRUIT (UNII: 7829X3G2X5)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
XANTHAN GUM (UNII: TTV12P4NEE)	

HYALURONATE SODIUM (UNII: YSE9PPT4TH)
PROPANEDIOL (UNII: 5965N8W85T)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)
COCO GLUCOSIDE (UNII: ICS790225B)
WATER (UNII: 059QF0KO0R)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
BENTONITE (UNII: A3N5ZCN45C)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ECTOINE (UNII: 7GXZ3858RY)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

Product Characteristics

Color	brown (52N)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-917-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-917-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 14N

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-918
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONI FRUIT (UNII: 7829X3G2X5)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
COCO GLUCOSIDE (UNII: ICS790225B)	
WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BENTONITE (UNII: A3N5ZCN45C)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ECTOINE (UNII: 7GXZ3858RY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	white (14N)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:59735-918-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-918-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

PROTECTINT 40W

homosalate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-919
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.58 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONI FRUIT (UNII: 7829X3G2X5)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
COCO GLUCOSIDE (UNII: ICS790225B)	

WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BENTONITE (UNII: A3N5ZCN45C)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ECTOINE (UNII: 7GXZ3858RY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	brown (40W)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-919-02	1 in 1 BOX	11/22/2023	
1	NDC:59735-919-01	35 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2023	

Labeler - MANA PRODUCTS, INC. (078870292)

Establishment

Name	Address	ID/FEI	Business Operations
MANA PRODUCTS, INC.		078870292	manufacture(59735-911, 59735-918, 59735-906, 59735-913, 59735-912, 59735-907, 59735-914, 59735-908, 59735-909, 59735-919, 59735-916, 59735-915, 59735-917, 59735-910)

Establishment

Name	Address	ID/FEI	Business Operations
MANA Products,INC		032870270	manufacture(59735-911, 59735-918, 59735-906, 59735-913, 59735-912, 59735-907, 59735-914, 59735-908, 59735-909, 59735-919, 59735-916, 59735-915, 59735-917, 59735-910)