

NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - IVORY- titanium dioxide lotion

NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - LINEN- titanium dioxide lotion

NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - OCHRE- titanium dioxide lotion

NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - NATURAL BEIGE- titanium dioxide lotion

NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - LIGHT GOLDEN- titanium dioxide lotion

NSE 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.

Nu Colour® Bioadaptive BB+ Foundation

Drug Facts

Active Ingredient

Titanium Dioxide 12%

Purpose

Sunscreen

Use

- Helps prevent sunburn.
- Higher SPF gives more sun protection.
- 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.
- Smooth over face and neck, blending well. Seal with powder if desired.

Warnings

- **For external use only.**
- Do not use on damaged or broken skin.
- Stop use and ask a doctor if a rash occurs.
- When using this product, keep out of eyes.
- Rinse with water to remove.
- **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- Children under 6 months of age: Ask a doctor
- 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 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.

Other Information

- Protect this product from excessive heat and direct sun.

Inactive Ingredients

Water (Aqua), Phenyl Trimethicone, Dimethicone, Butylene Glycol Dicaprylate/Dicaprate, Butylene Glycol, Acrylates Copolymer, Butyloctyl Salicylate, Squalane, Cetyl PEG/PPG-10/1 Dimethicone, Pentylene Glycol, Dimethicone/Vinyl Dimethicone Crosspolymer, Hexyl Laurate, Glycerin, Polyglyceryl-4 Isostearate, Magnesium Stearate, Distearidmonium Hectorite, Magnesium Sulfate, Phenoxyethanol, Tribehenin, Sorbitan Sesquioleate, Ethylhexyl Palmitate, Triethoxycaprylylsilane, Stearic Acid, Hydrogenated Olive Oil Unsaponifiables, Alumina, Methyl Methacrylate Crosspolymer, Synthetic Fluorophlogopite, Aluminum Hydroxide, Ethylhexylglycerin, Sodium Hyaluronate, Theobroma Cacao (Cocoa) Seed Extract, Rosa Damascena Flower Extract, Saccharomyces Ferment Filtrate, Trihydroxystearin, Glucomannan, Propanediol, 1,2-Hexanediol, Tin Oxide, Disodium EDTA, Mica (CI 77019), Iron Oxides (CI 77491, CI 77492, CI 77499).

Questions?

1-888-742-7626

PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton - Ivory

NU COLOUR®

NU

BIOADAPTIVE BB+
SKIN LOVING
FOUNDATION

Broad Spectrum
SPF 35

30 mL e 1 Fl Oz

Glue Seam

Drug Facts (continued)

6 months of age: Ask a doctor ■ 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 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

Other Information: ■ Protect this product from excessive heat and direct sun.

Drug Facts (continued)

1,2-Hexanediol, Tin Oxide, Disodium EDTA, Mica (CI 77019), Iron Oxides (CI 77491, CI 77492, CI 77499)

Questions? 1-888-742-7626



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Drug Facts (continued)

Inactive Ingredients: Water (Aqua), Phenyl Trimethicone, Dimethicone, Butylene Glycol Dicaprylate/Dicaprate, Butylene Glycol, Acrylates Copolymer, Butyloxy Salicylate, Squalane, Cetyl PEG/PPG-10/1 Dimethicone, Pentylene Glycol, Dimethicone/Vinyl Dimethicone Crosspolymer, Hexyl Laurate, Glycerin, Polyglyceryl-4 Isodecylate, Magnesium Stearate, Disodiummonium Hectorite, Magnesium Sulfate, Phenoxethanol, Triethanol Sorbitan Sesquiolate, Ethylhexyl Palmitate, Triethoxycaprylylsilane, Stearic Acid, Hydrogenated Olive Oil Unsaponifiables, Alumina, Methyl Methacrylate Crosspolymer, Synthetic Fluorphlogopite, Aluminum Hydroxide, Ethylhexylglycerin, Sodium Hyaluronate, Theobroma Cacao (Cocoa) Seed Extract, Rosa Damascena Flower Extract, Saccharomyces Ferment Filtrate, Trihydroxystearin, Glucomannan, Propylene Glycol



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94513365/1

30 mL e 1 Fl Oz



Broad Spectrum
SPF 35

BIOADAPTIVE BB+
SKIN LOVING
FOUNDATION

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Drug Facts

Active Ingredient

Titanium Dioxide 12%..... Sunscreen

Use: ■ Helps prevent sunburn. ■ Higher SPF gives more sun protection. ■ 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. ■ Smooth over face and neck, blending well. Seal with powder if desired.

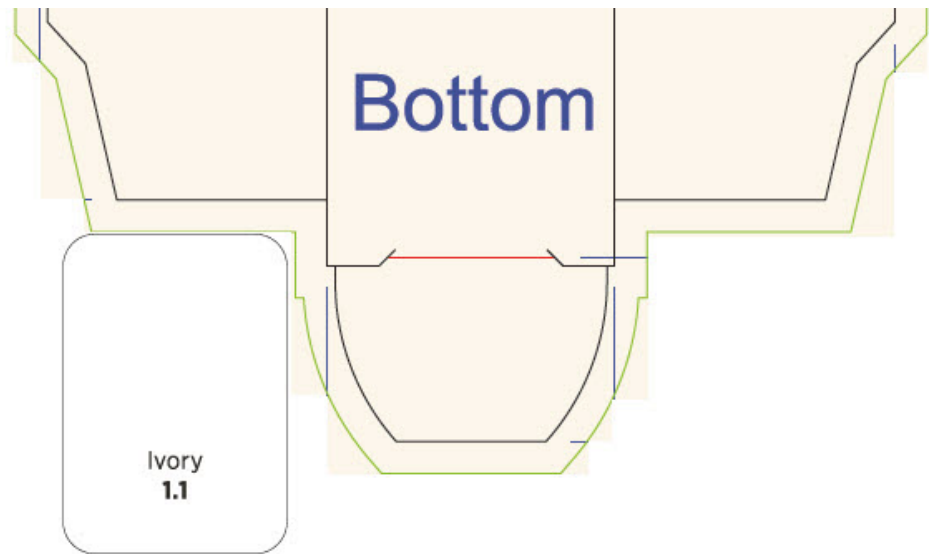
Purpose

Sunscreen

Drug Facts (continued)

Warnings: ■ For external use only. ■ Do not use on damaged or broken skin. ■ Stop use and ask a doctor if a rash occurs. ■ When using this product, keep out of eyes. ■ Rinse with water to remove. ■ Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ Apply liberally 15 minutes before sun exposure. ■ Children under



PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton - Linen

NU COLOUR®

NU

BIOADAPTIVE BB+
SKIN LOVING
FOUNDATION

Broad Spectrum
SPF 35

30 mL e 1 Fl Oz

Glue Seam

Drug Facts (continued)

6 months of age: Ask a doctor ■ 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 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

Other Information: ■ Protect this product from excessive heat and direct sun.

Drug Facts (continued)

1,2-Hexanediol, Tin Oxide, Disodium EDTA, Mica (CI 77019), Iron Oxides (CI 77491, CI 77492, CI 77499)

Questions? 1-888-742-7626



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Drug Facts (continued)

Inactive Ingredients: Water (Aqua), Phenyl Trimethicone, Dimethicone, Butylene Glycol Dicaprylate/Dicaprate, Butylene Glycol, Acrylates Copolymer, Butyloxy Salicylate, Squalane, Cetyl PEG/PPG-10/1 Dimethicone, Pentylene Glycol, Dimethicone/Vinyl Dimethicone Crosspolymer, Hexyl Laurate, Glycerin, Polyglyceryl-4 Isodecylate, Magnesium Stearate, Diglycidyl Ether of Dimethylacrylate, Magnesium Sulfate, Phenoxethanol, Triethanol, Sorbitan Sesquiolate, Ethylhexyl Palmitate, Triethoxycaprylylsilane, Stearic Acid, Hydrogenated Olive Oil Unsaponifiables, Alumina, Methyl Methacrylate Crosspolymer, Synthetic Fluorphlogopite, Aluminum Hydroxide, Ethylhexylglycerin, Sodium Hyaluronate, Theobroma Cacao (Cocoa) Seed Extract, Rosa Damascena Flower Extract, Saccharomyces Ferment Filtrate, Trihydroxystearin, Glucomannan, Propylene Glycol



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94513365/1

30 mL e 1 Fl Oz



Broad Spectrum
SPF 35

BIOADAPTIVE BB+
SKIN LOVING
FOUNDATION

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Drug Facts

Active Ingredient

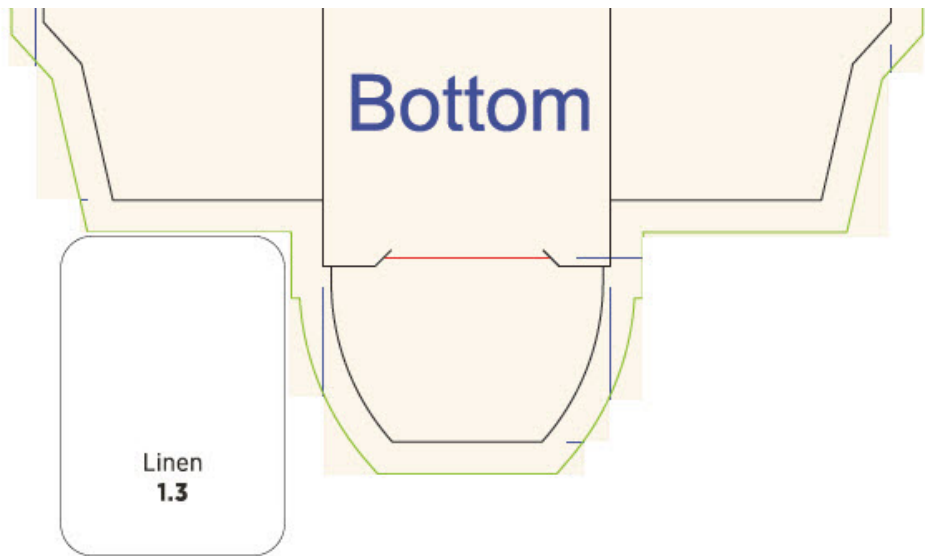
Titanium Dioxide 12%..... Sunscreen

Use: ■ Helps prevent sunburn. ■ Higher SPF gives more sun protection. ■ 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. ■ Smooth over face and neck, blending well. Seal with powder if desired.

Drug Facts (continued)

Warnings: ■ For external use only. ■ Do not use on damaged or broken skin. ■ Stop use and ask a doctor if a rash occurs. ■ When using this product, keep out of eyes. ■ Rinse with water to remove. ■ Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ Apply liberally 15 minutes before sun exposure. ■ Children under



PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton - Ochre

NU COLOUR®

NU

BIOADAPTIVE BB+
SKIN LOVING
FOUNDATION

Broad Spectrum
SPF 35

30 mL e 1 Fl Oz

Glue Seam

Drug Facts (continued)

6 months of age: Ask a doctor ■ 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 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

Other Information: ■ Protect this product from excessive heat and direct sun.

Drug Facts (continued)

1,2-Hexanediol, Tin Oxide, Disodium EDTA, Mica (CI 77019), Iron Oxides (CI 77491, CI 77492, CI 77499)

Questions? 1-888-742-7626



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Drug Facts (continued)

Inactive Ingredients: Water (Aqua), Phenyl Trimethicone, Dimethicone, Butylene Glycol Dicaprylate/Dicaprate, Butylene Glycol, Acrylates Copolymer, Butyloxy Salicylate, Squalane, Cetyl PEG/PPG-10/1 Dimethicone, Perylene Glycol, Dimethicone/Vinyl Dimethicone Crosspolymer, Hexyl Laurate, Glycerin, Polyglyceryl-4 Isodecylate, Magnesium Stearate, Diglycidyl Ether of Dimethylacrylate, Magnesium Sulfate, Phenoxethanol, Triethanolamine, Sorbitan Sesquioleate, Ethylhexyl Palmitate, Triethoxycaprylylsilane, Stearic Acid, Hydrogenated Olive Oil Unsaponifiables, Alumina, Methyl Methacrylate Crosspolymer, Synthetic Fluorphlogopite, Aluminum Hydroxide, Ethylhexylglycerin, Sodium Hyaluronate, Theobroma Cacao (Cocoa) Seed Extract, Rosa Damascena Flower Extract, Saccharomyces Ferment Filtrate, Trihydroxystearin, Glucomannan, Propylene Glycol



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30 mL e 1 Fl Oz



Broad Spectrum
SPF 35

BIOADAPTIVE BB+
SKIN LOVING
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Drug Facts

Active Ingredient

Titanium Dioxide 12%..... Sunscreen

Use: ■ Helps prevent sunburn. ■ Higher SPF gives more sun protection. ■ 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. ■ Smooth over face and neck, blending well. Seal with powder if desired.

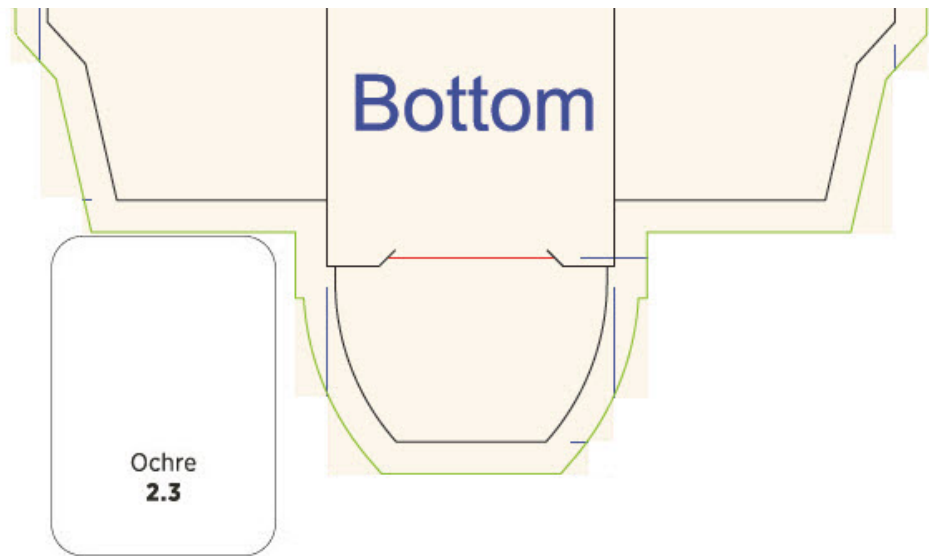
Purpose

Sunscreen

Drug Facts (continued)

Warnings: ■ For external use only. ■ Do not use on damaged or broken skin. ■ Stop use and ask a doctor if a rash occurs. ■ When using this product, keep out of eyes. ■ Rinse with water to remove. ■ Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ Apply liberally 15 minutes before sun exposure. ■ Children under



PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton - Natural-Beige

NU COLOUR®

NU

BIOADAPTIVE BB+
SKIN LOVING
FOUNDATION

Broad Spectrum
SPF 35

30 mL e 1 Fl Oz

Glue Seam

Drug Facts (continued)

6 months of age: Ask a doctor ■ 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 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

Other Information: ■ Protect this product from excessive heat and direct sun.

Drug Facts (continued)

1,2-Hexanediol, Tin Oxide, Disodium EDTA, Mica (CI 77019), Iron Oxides (CI 77491, CI 77492, CI 77499)

Questions? 1-888-742-7626



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Drug Facts (continued)

Inactive Ingredients: Water (Aqua), Phenyl Trimethicone, Dimethicone, Butylene Glycol Dicaprylate/Dicaprate, Butylene Glycol, Acrylates Copolymer, Butyloctyl Salicylate, Squalane, Cetyl PEG/PPG-10/1 Dimethicone, Pentylene Glycol, Dimethicone/Vinyl Dimethicone Crosspolymer, Hexyl Laurate, Glycerin, Polyglyceryl-4 Isodecylate, Magnesium Stearate, Disodiummonium Hectorite, Magnesium Sulfate, Phenoxethanol, Tribehenin, Sorbitan Sesquioleate, Ethylhexyl Palmitate, Triethoxycaprylylsilane, Stearic Acid, Hydrogenated Olive Oil Unsaponifiables, Alumina, Methyl Methacrylate Crosspolymer, Synthetic Fluorphlogopite, Aluminum Hydroxide, Ethylhexylglycerin, Sodium Hyaluronate, Theobroma Cacao (Cocoa) Seed Extract, Rosa Damascena Flower Extract, Saccharomyces Ferment Filtrate, Trihydroxystearin, Glucomannan, Propylene Glycol



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30 mL e 1 Fl Oz



Broad Spectrum
SPF 35

BIOADAPTIVE BB+
SKIN LOVING
FOUNDATION

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Drug Facts

Active Ingredient

Titanium Dioxide 12%..... Sunscreen

Use: ■ Helps prevent sunburn ■ Higher SPF gives more sun protection. ■ 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. ■ Smooth over face and neck, blending well. Seal with powder if desired.

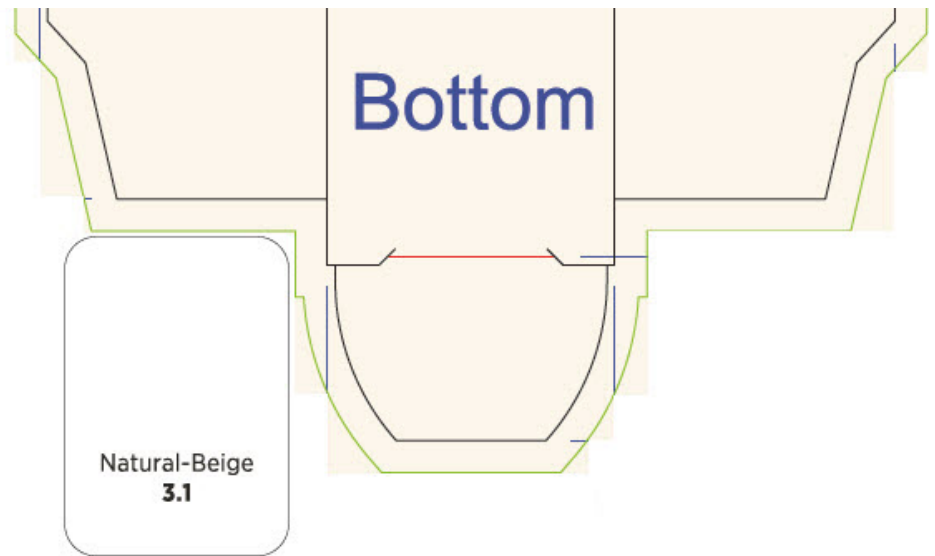
Purpose

Sunscreen

Drug Facts (continued)

Warnings: ■ For external use only. ■ Do not use on damaged or broken skin. ■ Stop use and ask a doctor if a rash occurs. ■ When using this product, keep out of eyes. ■ Rinse with water to remove. ■ Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ Apply liberally 15 minutes before sun exposure. ■ Children under



PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton - Light-Golden

NU COLOUR®

NU

BIOADAPTIVE BB+
SKIN LOVING
FOUNDATION

Broad Spectrum
SPF 35

30 mL e 1 Fl Oz

Glue Seam

Drug Facts (continued)

6 months of age. Ask a doctor. ■ 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 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.

Other Information: ■ Protect this product from excessive heat and direct sun.

Drug Facts (continued)

Inactive Ingredients: Water (Aqua), Phenyl Trimethicone, Dimethicone, Dimethicone, Butylene Glycol Dicaprylate/Dicaprylate, Butylene Glycol, Acrylates Copolymer, Butyloxy Salicylate, Squalane, Cetyl PEG/PPG-10/1 Dimethicone, Pentylene Glycol, Dimethicone/Vinyl Dimethicone Crosspolymer, Hexyl Laurate, Glycerin, Polyglyceryl-4 Isostearate, Magnesium Stearate, Distardimonium Hectorite, Magnesium Sulfate, Phenoxethanol, Tribehenin, Sorbitan Sesquioleate, Ethylhexyl Palmitate, Triethoxycaprylylsilane, Stearic Acid, Hydrogenated Olive Oil Unsaponifiables, Alumina, Methyl Methacrylate Crosspolymer, Synthetic Fluorphlogopite, Aluminum Hydroxide, Ethylhexylglycerin, Sodium Hyaluronate, Theobroma Cacao (Cocoa) Seed Extract, Rosa Damascena Flower Extract, Saccharomyces Ferment Filtrate, Trihydroxystearin, Glucosamine, Propargenediol.

Drug Facts (continued)

1,2-Hexanediol, Tin Oxide, Disodium EDTA, Mica (CI 77019), Iron Oxides (CI 77491, CI 77492, CI 77499).

Questions? 1-888-742-7626



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30 mL e 1 Fl Oz

Broad Spectrum
SPF 35



BIOADAPTIVE BB+
SKIN LOVING
FOUNDATION

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Top

Drug Facts

Active Ingredient

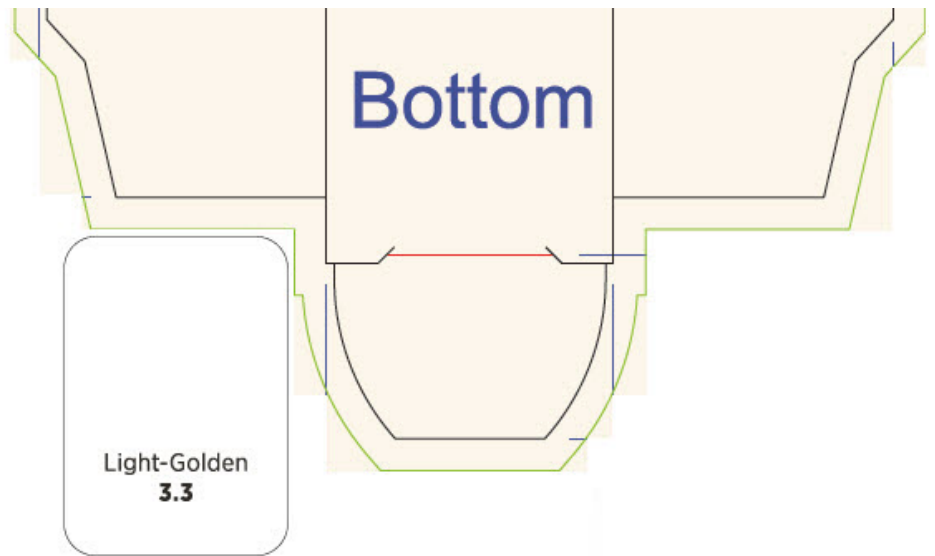
Titanium Dioxide 12%..... Sunscreen

Use: ■ Helps prevent sunburn. ■ Higher SPF gives more sun protection. ■ 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. ■ Smooth over face and neck, blending well. Seal with powder if desired.

Drug Facts (continued)

Warnings: ■ For external use only. ■ Do not use on damaged or broken skin. ■ Stop use and ask a doctor if a rash occurs. ■ When using this product, keep out of eyes. ■ Rinse with water to remove. ■ Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ Apply liberally 15 minutes before sun exposure. ■ Children under



NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - IVORY

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62839-3365
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	120 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Phenyl Trimethicone (UNII: DR0K5NOJ4R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Butylene Glycol Dicaprylate/Dicaprate (UNII: 75D21FL1PI)	
MICA (UNII: V8A1AW0880)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Squalane (UNII: GW89575KF9)	
Pentylene Glycol (UNII: 50C1307PZG)	
Hexyl Laurate (UNII: 4CG9F9W01Q)	
Glycerin (UNII: PDC6A3C0OX)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Magnesium Stearate (UNII: 70097M6I30)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
Phenoxyethanol (UNII: HIE492ZZ3T)	

Sorbitan Sesquioleate (UNII: 0W8RRI5W5A)
Tribehenin (UNII: 8OC9U7TQZ0)
Ethylhexyl Palmitate (UNII: 2865993309)
Stearic Acid (UNII: 4ELV7Z65AP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
Hydrogenated Olive Oil Unsaponifiables (UNII: B8MIX97W95)
ALUMINUM OXIDE (UNII: LMI26O6933)
Triethoxycaprylylsilane (UNII: LDC331P08E)
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)
Aluminum Hydroxide (UNII: 5QB0T2IUN0)
Ethylhexylglycerin (UNII: 147D247K3P)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
ROSA X DAMASCENA FLOWER (UNII: JWB78P295A)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
COCOA (UNII: D9108TZ9KG)
Trihydroxystearin (UNII: 06YD7896S3)
Propanediol (UNII: 5965N8W85T)
1,2-Hexanediol (UNII: TR046Y3K1G)
STANNIC OXIDE (UNII: KM7N50LOS6)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
KONJAC MANNAN (UNII: 36W3E5TAMG)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62839-3365-1	1 in 1 CARTON	02/03/2022	
1		30 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 FINAL	part352	02/03/2022	

NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - LINEN

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62839-3364
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	120 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Phenyl Trimethicone (UNII: DR0K5NOJ4R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Butylene Glycol Dicaprylate/Dicaprate (UNII: 75D21FL1PI)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
MICA (UNII: V8A1AW0880)	
Squalane (UNII: GW89575KF9)	
Pentylene Glycol (UNII: 50C1307PZG)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
Hexyl Laurate (UNII: 4CG9F9W01Q)	
Glycerin (UNII: PDC6A3C0OX)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Magnesium Stearate (UNII: 70097M6I30)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Sorbitan Sesquioleate (UNII: 0W8RRI5W5A)	
Tribehenin (UNII: 8OC9U7TQZ0)	
Ethylhexyl Palmitate (UNII: 2865993309)	
Stearic Acid (UNII: 4ELV7Z65AP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
Hydrogenated Olive Oil Unsaponifiables (UNII: B8MIX97W95)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
Ethylhexylglycerin (UNII: 147D247K3P)	
ROSA X DAMASCENA FLOWER (UNII: JWB78P295A)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
COCOA (UNII: D9108TZ9KG)	
Trihydroxystearin (UNII: 06YD7896S3)	
Propanediol (UNII: 5965N8W85T)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
KONJAC MANNAN (UNII: 36W3E5TAMG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62839-3364-1	1 in 1 CARTON	02/03/2022	
1		30 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 FINAL	part352	02/03/2022	

NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - OCHRE

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62839-3363
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	120 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Phenyl Trimethicone (UNII: DR0K5NOJ4R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Butylene Glycol Dicaprylate/Dicaprate (UNII: 75D21FL1PI)	
MICA (UNII: V8A1AW0880)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Squalane (UNII: GW89575KF9)	
Pentylene Glycol (UNII: 50C1307PZG)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
Hexyl Laurate (UNII: 4CG9F9W01Q)	
Glycerin (UNII: PDC6A3C0OX)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Magnesium Stearate (UNII: 70097M6I30)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Sorbitan Sesquiolate (UNII: 0W8RRI5W5A)	
Tribehenin (UNII: 8OC9U7TQZ0)	

Ethylhexyl Palmitate (UNII: 2865993309)
FERRIC OXIDE RED (UNII: 1K09F3G675)
Stearic Acid (UNII: 4ELV7Z65AP)
Hydrogenated Olive Oil Unsaponifiables (UNII: B8MIX97W95)
Triethoxycaprylylsilane (UNII: LDC331P08E)
ALUMINUM OXIDE (UNII: LMI26O6933)
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)
Aluminum Hydroxide (UNII: 5QB0T2IUN0)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
Ethylhexylglycerin (UNII: 147D247K3P)
ROSA X DAMASCENA FLOWER (UNII: JWB78P295A)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
COCOA (UNII: D9108TZ9KG)
Trihydroxystearin (UNII: 06YD7896S3)
Propanediol (UNII: 5965N8W85T)
1,2-Hexanediol (UNII: TR046Y3K1G)
STANNIC OXIDE (UNII: KM7N50LOS6)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
KONJAC MANNAN (UNII: 36W3E5TAMG)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62839-3363-1	1 in 1 CARTON	02/03/2022	
1		30 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 FINAL	part352	02/03/2022	

NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - NATURAL BEIGE

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62839-3362
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	120 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
Phenyl Trimethicone (UNII: DR0K5NOJ4R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Butylene Glycol Dicaprylate/Dicaprate (UNII: 75D21FL1PI)	
MICA (UNII: V8A1AW0880)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Squalane (UNII: GW89575KF9)	
Pentylene Glycol (UNII: 50C1307PZG)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
Hexyl Laurate (UNII: 4CG9F9W01Q)	
Glycerin (UNII: PDC6A3C0OX)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Magnesium Stearate (UNII: 70097M6I30)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Sorbitan Sesquileate (UNII: 0W8RRI5W5A)	
Tribehenin (UNII: 8OC9U7TQZ0)	
Ethylhexyl Palmitate (UNII: 2865993309)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Hydrogenated Olive Oil Unsaponifiables (UNII: B8MIX97W95)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
Aluminum Hydroxide (UNII: 5QB0T2IU0)	
Ethylhexylglycerin (UNII: 147D247K3P)	
ROSA X DAMASCENA FLOWER (UNII: JWB78P295A)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
COCOA (UNII: D9108TZ9KG)	
Trihydroxystearin (UNII: 06YD7896S3)	
Propanediol (UNII: 5965N8W85T)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
KONJAC MANNAN (UNII: 36W3E5TAMG)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:62839-3362-1	1 in 1 CARTON	02/03/2022	
1		30 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 FINAL	part352	02/03/2022	

NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - LIGHT GOLDEN

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62839-3361
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	120 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Phenyl Trimethicone (UNII: DR0K5NOJ4R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Butylene Glycol Dicaprylate/Dicaprate (UNII: 75D21FL1PI)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Squalane (UNII: GW89575KF9)	
MICA (UNII: V8A1AW0880)	
Pentylene Glycol (UNII: 50C1307PZG)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
Hexyl Laurate (UNII: 4CG9F9W01Q)	
Glycerin (UNII: PDC6A3C0OX)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Magnesium Stearate (UNII: 70097M6I30)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Sorbitan Sesquioleate (UNII: 0W8RRI5W5A)	
Tribehenin (UNII: 8OC9U7TQZ0)	

Ethylhexyl Palmitate (UNII: 2865993309)
FERRIC OXIDE RED (UNII: 1K09F3G675)
Stearic Acid (UNII: 4ELV7Z65AP)
Hydrogenated Olive Oil Unsaponifiables (UNII: B8MIX97W95)
ALUMINUM OXIDE (UNII: LMI26O6933)
Triethoxycaprylylsilane (UNII: LDC331P08E)
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)
Aluminum Hydroxide (UNII: 5QB0T2IUN0)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
Ethylhexylglycerin (UNII: 147D247K3P)
ROSA X DAMASCENA FLOWER (UNII: JWB78P295A)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
COCOA (UNII: D9108TZ9KG)
Trihydroxystearin (UNII: 06YD7896S3)
Propanediol (UNII: 5965N8W85T)
1,2-Hexanediol (UNII: TR046Y3K1G)
STANNIC OXIDE (UNII: KM7N50LOS6)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
KONJAC MANNAN (UNII: 36W3E5TAMG)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62839-3361-1	1 in 1 CARTON	02/03/2022	
1		30 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 FINAL	part352	02/03/2022	

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