

**NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - JAVA- titanium dioxide lotion**  
**NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - ESPRESSO- 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.*

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**Nu Colour® Bioadaptive BB+ Foundation**

***Drug Facts***

**Active Ingredient**

Titanium Dioxide 5%

**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, Distearidimonium Hectorite, Magnesium Sulfate, Phenoxyethanol, 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, 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 - Java**

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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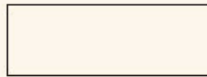
30 mL e 1 Fl Oz



Please recycle—check your local capabilities.

94513954/1

Broad Spectrum  
SPF 35



**BIOADAPTIVE BB+**  
SKIN LOVING  
FOUNDATION

# NU

NU COLOUR®

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## Drug Facts (continued)

**Inactive Ingredients:** Water (Aqua), Phenyl Trimethicone, Dimethicone, Butylene Glycol Dicaprylate/Dicaprate, Butylene Glycol, Acrylates Copolymer, Butylacetyl Salicylate, Squalane, Cetyl PEG/PPG-10/7 Dimethicone, Pentaerythritol Dimethacrylate, Dimethicone/Vinyl Dimethicone Crosspolymer, Hexyl Laurate, Glycerin, Polyphenyl-4 Isobutylate, Magnesium Stearate, Disolefinodimethylmethacrylate, Magnesium Sulfate, Phenoxypentanol, 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, Gluconolactone, Propargylol.

## Drug Facts

### Active Ingredient

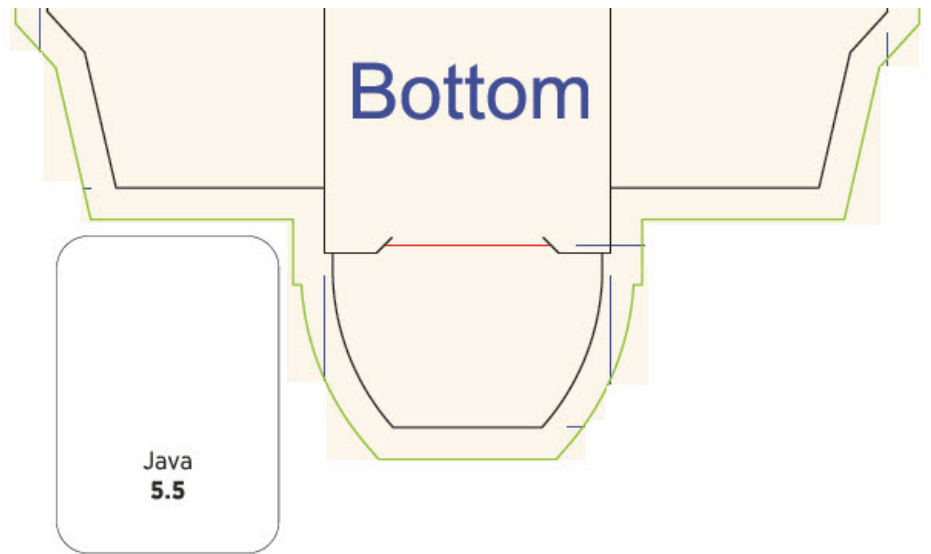
Titanium Dioxide 5%..... Sunscreen

**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.

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**PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton - Espresso**

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.

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## 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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Please recycle—check your local capabilities.  
94513954/1

30 mL e 1 Fl Oz

Broad Spectrum  
SPF 35



BIOADAPTIVE BB+  
SKIN LOVING  
FOUNDATION

# NU

NU COLOUR®

Top

## Drug Facts

### Active Ingredient

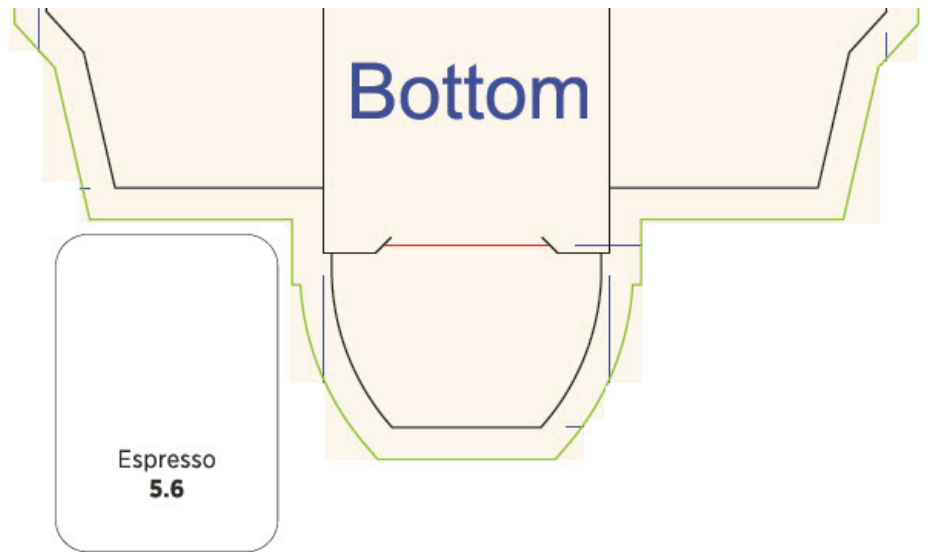
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## Drug Facts (continued)

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



## NU COLOUR BIOADAPTIVE BB PLUS FOUNDATION - JAVA

titanium dioxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62839-3954
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	50 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>Phenyl Trimethicone</b> (UNII: DR0K5NOJ4R)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>Butylene Glycol Dicaprylate/Dicaprate</b> (UNII: 75D21FL1PI)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>Butyloctyl Salicylate</b> (UNII: 2EH13UN8D3)	
<b>Squalane</b> (UNII: GW89575KF9)	
<b>Pentylene Glycol</b> (UNII: 50C1307PZG)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>Hexyl Laurate</b> (UNII: 4CG9F9W01Q)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Polyglyceryl-4 Isostearate</b> (UNII: 820DPX33S7)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	

<b>Disteardimonium Hectorite</b> (UNII: X687XDK09L)
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)
<b>Triethoxycaprylylsilane</b> (UNII: LDC331P08E)
<b>Sorbitan Sesquioleate</b> (UNII: 0W8RRI5W5A)
<b>Tribehenin</b> (UNII: 8OC9U7TQZ0)
<b>Ethylhexyl Palmitate</b> (UNII: 2865993309)
<b>Hydrogenated Olive Oil Unsaponifiables</b> (UNII: B8MIX97W95)
<b>METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER</b> (UNII: EG97988M5Q)
<b>MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE</b> (UNII: YK3DC63Y5M)
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)
<b>ROSA X DAMASCENA FLOWER</b> (UNII: JWB78P295A)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>COCOA</b> (UNII: D9108TZ9KG)
<b>Trihydroxystearin</b> (UNII: 06YD7896S3)
<b>Propanediol</b> (UNII: 5965N8W85T)
<b>1,2-Hexanediol</b> (UNII: TR046Y3K1G)
<b>STANNIC OXIDE</b> (UNII: KM7N50LOS6)
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)
<b>KONJAC MANNAN</b> (UNII: 36W3E5TAMG)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62839-3954-1	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 - ESPRESSO

titanium dioxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62839-3953
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	50 mg in 1 mL

**Inactive Ingredients**

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<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>Butyloctyl Salicylate</b> (UNII: 2EH13UN8D3)	
<b>Squalane</b> (UNII: GW89575KF9)	
<b>Pentylene Glycol</b> (UNII: 50C1307PZG)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>Hexyl Laurate</b> (UNII: 4CG9F9W01Q)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Polyglyceryl-4 Isostearate</b> (UNII: 820DPX33S7)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	
<b>Disteardimonium Hectorite</b> (UNII: X687XDK09L)	
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Triethoxycaprylylsilane</b> (UNII: LDC331P08E)	
<b>Sorbitan Sesquioleate</b> (UNII: 0W8RRI5W5A)	
<b>Tribehenin</b> (UNII: 8OC9U7TQZ0)	
<b>Ethylhexyl Palmitate</b> (UNII: 2865993309)	
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OTC MONOGRAPH FINAL	part352	02/03/2022	

**Labeler** - NSE Products, Inc. (803486393)

Revised: 2/2022

NSE Products, Inc.