SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL) O00- octinoxate and titanium dioxide paste
SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL) O20- octinoxate and titanium dioxide paste
SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL) O40- octinoxate and titanium dioxide paste
SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL) O60- octinoxate and titanium dioxide paste
SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL) BF20- octinoxate and titanium dioxide paste
SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL) I00- octinoxate and titanium dioxide paste
SHISEIDO AMERICA 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.

SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL)

Drug Facts

ACTIVE INGREDIENTS:	**Purpose**
OCTINOXATE 3.9%	Sunscreen
TITANIUM DIOXIDE 6.6%	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

For sunscreen use:

- 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

SYNTHETIC FLUORPHLOGOPITE, TALC, TRIETHYLHEXANOIN, DIMETHICONE, SILICA, SYNTHETIC WAX, VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER, TRANEXAMIC ACID, ALUMINUM HYDROXIDE, SORBITAN SESQUIISOSTEARATE, POLYMETHYL METHACRYLATE, SODIUM HYALURONATE, ALUMINUM DISTEARATE, POLYSILICONE-2, SODIUM MAGNESIUM SILICATE, GLYCERIN, TOCOPHEROL, BHT, CHLORPHENESIN, FRAGRANCE, MICA, TITANIUM DIOXIDE, IRON OXIDES,

Other information

- protect this product in this container from excessive heat and direct sun.

Questions or comments?

Call toll free 1-800-906-7503

SHISEIDO AMERICA INC. NEW YORK, N.Y. 10022
SHISEIDO DIST. NEW YORK • PARIS • MILANO

PRINCIPAL DISPLAY PANEL - 10g Tray Carton - O00

SHISEIDO

WHITE LUCENT

Brightening
Spot-Control Foundation
(Refill)

BROAD SPECTRUM
SPF 26

SUNSCREEN

10g NET WT. .35 OZ.

RECOMMENDED
SKIN CANCER FOUNDATION
DAILY USE

Brightening Spot-Control Foundation (Refill)

O00
GLO.10452

SHISEIDO

WHITE LUCENT

Brightening Spot-Control Foundation (Refill)

BROAD SPECTRUM
SPF 26

SUNSCREEN

10g NET WT. .35 OZ.

Specially formulated by Shiseido Laboratories, Japan.

Drug Facts (continued)

Inactive ingredients

SYNTHETIC FLUORPHLOGOPITE • TALC • TRIETHYLHEXANOIN • DIMETHICONE • SILICA • SYNTHETIC WAX • VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER • TRANEXAMIC ACID • ALUMINUM HYDROXIDE • SORBITAN SESQUIISOSTEARATE • POLYMETHYL METHACRYLATE • SODIUM HYALURONATE • ALUMINUM DISTEARATE • POLYSILICONE-2 • SODIUM MAGNESIUM SILICATE • GLYCERIN • TOCOPHEROL • BHT • CHLORPHENESIN • FRAGRANCE • MICA • TITANIUM DIOXIDE • IRON OXIDES •

Other Information

protect this product in this container from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-800-906-7503

58×23.5×71

The ultimate brightening solution for even-toned skin with perfect radiance.

An innovative brightening powdery foundation, formulated with m-Tranexamic Acid, a powerful brightening ingredient which counteracts the unique condition of dark spots. Helps protect skin from harmful UV rays, leaving skin even-toned, spotless and perfectly radiant after just one application.

Drug Facts

Active ingredients — Purpose

OCTINOXATE 3.9% ..... Sunscreen
TITANIUM DIOXIDE 6.6% ..... 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

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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. ▶

SHISEIDO AMERICA INC. NEW YORK, N.Y. 10022
MADE IN U.S.A.
SHISEIDO DIST. NEW YORK·PARIS·MILANO
www.shiseido.com

Drug Facts (continued)

Directions

For sunscreen use:

- 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 ▶

10452-40-5041

AAB

PRINCIPAL DISPLAY PANEL - 10g Tray Carton - O20

SHISEIDO

WHITE LUCENT

Brightening
Spot-Control Foundation
(Refill)

BROAD SPECTRUM
SPF 26

SUNSCREEN

10g NET WT. .35 OZ.

RECOMMENDED
SKIN CANCER FOUNDATION
DAILY USE

Brightening Spot-Control Foundation (Refill)

O20
GLO.10453

Specially formulated by Shiseido Laboratories, Japan.

SHISEIDO

WHITE LUCENT

Brightening Spot-Control Foundation (Refill)

BROAD SPECTRUM
SPF 26

SUNSCREEN

10g NET WT. .35 OZ.

Drug Facts (continued)

Inactive ingredients

SYNTHETIC FLUORPHLOGOPITE · TALC · TRIETHYLHEXANOIN · DIMETHICONE · SILICA · SYNTHETIC WAX · VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER · TRANEXAMIC ACID · ALUMINUM HYDROXIDE · SORBITAN SESQUIISOSTEARATE · POLYMETHYL METHACRYLATE · SODIUM HYALURONATE · ALUMINUM DISTEARATE · POLYSILICONE-2 · SODIUM MAGNESIUM SILICATE · GLYCERIN · TOCOPHEROL · BHT · CHLORPHENESIN · FRAGRANCE · MICA · TITANIUM DIOXIDE · IRON OXIDES ·

Other Information

protect this product in this container from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-800-906-7503

58×23.5×71

TS 1 2 3 4 5 6 7 8 9 0

The ultimate brightening solution for even-toned skin with perfect radiance.

An innovative brightening powdery foundation, formulated with m-Tranexamic Acid, a powerful brightening ingredient which counteracts the unique condition of dark spots. Helps protect skin from harmful UV rays, leaving skin even-toned, spotless and perfectly radiant after just one application.

Drug Facts

Active ingredients — Purpose

OCTINOXATE 3.9% ..... Sunscreen
TITANIUM DIOXIDE 6.6% ..... 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. ▶

SHISEIDO AMERICA INC. NEW YORK, N.Y. 10022
MADE IN U.S.A.
SHISEIDO DIST. NEW YORK·PARIS·MILANO
www.shiseido.com

Drug Facts (continued)

Directions

For sunscreen use:

- 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 ▶

10452-40-5041

AAB

PRINCIPAL DISPLAY PANEL - 10g Tray Carton - O40

SHISEIDO

WHITE LUCENT

Brightening
Spot-Control Foundation
(Refill)

BROAD SPECTRUM
SPF 26

SUNSCREEN

10g NET WT. .35 OZ.

RECOMMENDED
SKIN CANCER FOUNDATION
DAILY USE

Brightening Spot-Control Foundation (Refill)

O40
GLO.10454

Specially formulated by Shiseido Laboratories, Japan.

SHISEIDO

WHITE LUCENT

Brightening Spot-Control Foundation (Refill)

BROAD SPECTRUM
SPF 26

SUNSCREEN

10g NET WT. .35 OZ.

Drug Facts (continued)

Inactive ingredients

SYNTHETIC FLUORPHLOGOPITE • TALC • TRIETHYLHEXANOIN • DIMETHICONE • SILICA • SYNTHETIC WAX • VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER • TRANEXAMIC ACID • ALUMINUM HYDROXIDE • SORBITAN SESQUIISOSTEARATE • POLYMETHYL METHACRYLATE • SODIUM HYALURONATE • ALUMINUM DISTEARATE • POLYSILICONE-2 • SODIUM MAGNESIUM SILICATE • GLYCERIN • TOCOPHEROL • BHT • CHLORPHENESIN • FRAGRANCE • MICA • TITANIUM DIOXIDE • IRON OXIDES •

Other Information

■ protect this product in this container from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-800-906-7503

58×23.5×71

The ultimate brightening solution for even-toned skin with perfect radiance.

An innovative brightening powdery foundation, formulated with m-Tranexamic Acid, a powerful brightening ingredient which counteracts the unique condition of dark spots. Helps protect skin from harmful UV rays, leaving skin even-toned, spotless and perfectly radiant after just one application.

Drug Facts

Active ingredients — Purpose

OCTINOXATE 3.9% ..... Sunscreen
TITANIUM DIOXIDE 6.6% ..... 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

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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. ▶

SHISEIDO AMERICA INC. NEW YORK, N.Y. 10022
MADE IN U.S.A.
SHISEIDO DIST. NEW YORK·PARIS·MILANO
www.shiseido.com

Drug Facts (continued)

Directions

For sunscreen use:

- 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 ▶

10452-40-5041

AAB

PRINCIPAL DISPLAY PANEL - 10g Tray Carton - O60

SHISEIDO

WHITE LUCENT

Brightening
Spot-Control Foundation
(Refill)

BROAD SPECTRUM
SPF 26

SUNSCREEN

10g NET WT. .35 OZ.

RECOMMENDED
SKIN CANCER FOUNDATION
DAILY USE

Brightening Spot-Control Foundation (Refill)

O60
GLO.10455

Specially formulated by Shiseido Laboratories, Japan.

SHISEIDO

WHITE LUCENT

Brightening Spot-Control Foundation (Refill)

BROAD SPECTRUM
SPF 26

SUNSCREEN

10g NET WT. .35 OZ.

Drug Facts (continued)

Inactive ingredients

SYNTHETIC FLUORPHLOGOPITE • TALC • TRIETHYLHEXANOIN • DIMETHICONE • SILICA • SYNTHETIC WAX • VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER • TRANEXAMIC ACID • ALUMINUM HYDROXIDE • SORBITAN SESQUIISOSTEARATE • POLYMETHYL METHACRYLATE • SODIUM HYALURONATE • ALUMINUM DISTEARATE • POLYSILICONE-2 • SODIUM MAGNESIUM SILICATE • GLYCERIN • TOCOPHEROL • BHT • CHLORPHENESIN • FRAGRANCE • MICA • TITANIUM DIOXIDE • IRON OXIDES •

Other Information

■ protect this product in this container from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-800-906-7503

58×23.5×71

TB 1 2 3 4 5 6 7 8 9 0

The ultimate brightening solution for even-toned skin with perfect radiance.

An innovative brightening powdery foundation, formulated with m-Tranexamic Acid, a powerful brightening ingredient which counteracts the unique condition of dark spots. Helps protect skin from harmful UV rays, leaving skin even-toned, spotless and perfectly radiant after just one application.

Drug Facts

Active ingredients — Purpose

OCTINOXATE 3.9% ..... Sunscreen
TITANIUM DIOXIDE 6.6% ..... 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. ▶

SHISEIDO AMERICA INC. NEW YORK, N.Y. 10022
MADE IN U.S.A.
SHISEIDO DIST. NEW YORK·PARIS·MILANO
www.shiseido.com

Drug Facts (continued)

Directions

For sunscreen use:

- 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 ▶

10452-40-5041

AAB

PRINCIPAL DISPLAY PANEL - 10g Tray Carton - BF20

SHISEIDO

WHITE LUCENT

Brightening
Spot-Control Foundation
(Refill)

BROAD SPECTRUM
SPF 26

SUNSCREEN

10g NET WT. .35 OZ.

RECOMMENDED
SKIN CANCER FOUNDATION
DAILY USE

Brightening Spot-Control Foundation (Refill)

BF20
GLO.10456

Specially formulated by Shiseido Laboratories, Japan.

SHISEIDO

WHITE LUCENT

Brightening Spot-Control Foundation (Refill)

BROAD SPECTRUM
SPF 26

SUNSCREEN

10g NET WT. .35 OZ.

Drug Facts (continued)

Inactive ingredients

SYNTHETIC FLUORPHLOGOPITE • TALC • TRIETHYLHEXANOIN • DIMETHICONE • SILICA • SYNTHETIC WAX • VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER • TRANEXAMIC ACID • ALUMINUM HYDROXIDE • SORBITAN SESQUIISOSTEARATE • POLYMETHYL METHACRYLATE • SODIUM HYALURONATE • ALUMINUM DISTEARATE • POLYSILICONE-2 • SODIUM MAGNESIUM SILICATE • GLYCERIN • TOCOPHEROL • BHT • CHLORPHENESIN • FRAGRANCE • MICA • TITANIUM DIOXIDE • IRON OXIDES •

Other Information

■ protect this product in this container from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-800-906-7503

58×23.5×71

The ultimate brightening solution for even-toned skin with perfect radiance.

An innovative brightening powdery foundation, formulated with m-Tranexamic Acid, a powerful brightening ingredient which counteracts the unique condition of dark spots. Helps protect skin from harmful UV rays, leaving skin even-toned, spotless and perfectly radiant after just one application.

Drug Facts

Active ingredients	Purpose
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TITANIUM DIOXIDE 6.6%	Sunscreen

Uses

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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. ▶

SHISEIDO AMERICA INC. NEW YORK, N.Y. 10022
MADE IN U.S.A.
SHISEIDO DIST. NEW YORK·PARIS·MILANO
www.shiseido.com

Drug Facts (continued)

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
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  - wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor ▶

10452-40-5041

AAB

PRINCIPAL DISPLAY PANEL - 10g Tray Carton - I00

SHISEIDO

WHITE LUCENT

Brightening
Spot-Control Foundation
(Refill)

BROAD SPECTRUM
SPF 26

SUNSCREEN

10g NET WT. .35 OZ.

RECOMMENDED
SKIN CANCER FOUNDATION
DAILY USE

Brightening Spot-Control Foundation (Refill)

I00
GLO.10457

Specially formulated by Shiseido Laboratories, Japan.

SHISEIDO

WHITE LUCENT

Brightening Spot-Control Foundation (Refill)

BROAD SPECTRUM
SPF 26

SUNSCREEN

10g NET WT. .35 OZ.

Drug Facts (continued)

Inactive ingredients

SYNTHETIC FLUORPHLOGOPITE · TALC · TRIETHYLHEXANOIN · DIMETHICONE · SILICA · SYNTHETIC WAX · VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER · TRANEXAMIC ACID · ALUMINUM HYDROXIDE · SORBITAN SESQUIISOSTEARATE · POLYMETHYL METHACRYLATE · SODIUM HYALURONATE · ALUMINUM DISTEARATE · POLYSILICONE-2 · SODIUM MAGNESIUM SILICATE · GLYCERIN · TOCOPHEROL · BHT · CHLORPHENESIN · FRAGRANCE · MICA · TITANIUM DIOXIDE · IRON OXIDES ·

Other Information

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Questions or Comments?

Call toll free 1-800-906-7503

58×23.5×71

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Active ingredients	Purpose
OCTINOXATE 3.9%	Sunscreen
TITANIUM DIOXIDE 6.6%	Sunscreen

Uses

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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. ▶

SHISEIDO AMERICA INC. NEW YORK, N.Y. 10022
MADE IN U.S.A.
SHISEIDO DIST. NEW YORK·PARIS·MILANO
www.shiseido.com

Drug Facts (continued)

Directions

For sunscreen use:

- 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 ▶

10452-40-5041

AAB

SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL) O00

octinoxate and titanium dioxide paste

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52686-252
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.39 g in 10 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.66 g in 10 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRANEXAMIC ACID (UNII: 6T84R30KC1)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-252-30	1 in 1 CARTON	03/01/2011	12/01/2015
1		10 g in 1 TRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC MONOGRAPH NOT FINAL	part352	03/01/2011	12/01/2015

SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL) O20

octinoxate and titanium dioxide paste

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52686-253
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.39 g in 10 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.66 g in 10 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRANEXAMIC ACID (UNII: 6T84R30KC1)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-253-30	1 in 1 CARTON	03/01/2011	12/01/2015
1		10 g in 1 TRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/01/2011	12/01/2015

SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL) O40

octinoxate and titanium dioxide paste

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52686-254
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.39 g in 10 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.66 g in 10 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRANEXAMIC ACID (UNII: 6T84R30KC1)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:52686-254			

1	NDC:52686-254-30	1 in 1 CARTON	03/01/2011	01/01/2016
1		10 g in 1 TRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/01/2011	01/01/2016

SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL) O60

octinoxate and titanium dioxide paste

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52686-255
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.39 g in 10 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.66 g in 10 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRANEXAMIC ACID (UNII: 6T84R30KC1)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-255-30	1 in 1 CARTON	03/01/2011	12/01/2015
1		10 g in 1 TRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/01/2011	

SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL) BF20

octinoxate and titanium dioxide paste

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52686-256
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.39 g in 10 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.66 g in 10 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRANEXAMIC ACID (UNII: 6T84R30KC1)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-256-30	1 in 1 CARTON	03/01/2011	12/01/2015
1		10 g in 1 TRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/01/2011	12/01/2015

SHISEIDO WHITE LUCENT BRIGHTENING SPOT-CONTROL FOUNDATION (REFILL) I00

octinoxate and titanium dioxide paste

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52686-257
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.39 g in 10 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.66 g in 10 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRANEXAMIC ACID (UNII: 6T84R30KC1)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	

ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-257-30	1 in 1 CARTON	03/01/2011	10/01/2015
1		10 g in 1 TRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/01/2011	10/01/2015

Labeler - SHISEIDO AMERICA INC. (782677132)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(52686-252, 52686-253, 52686-254, 52686-255, 52686-256, 52686-257) , ANALYSIS(52686-252, 52686-253, 52686-254, 52686-255, 52686-256, 52686-257)

Revised: 9/2023 SHISEIDO AMERICA INC.