

**LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25
 CLAIRE 1 - BEIGE- octinoxate and zinc oxide liquid**
**LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25
 CLAIRE 2 - BEIGE- octinoxate and zinc oxide liquid**
**LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25
 CLAIRE 3 - BEIGE- octinoxate and zinc oxide liquid**
**LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25
 CLAIRE 4 - BEIGE- octinoxate and zinc oxide liquid**
**LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25
 MEDIUM 5 - BEIGE- octinoxate and zinc oxide liquid**
**LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25
 MEDIUM 6 - BEIGE- octinoxate and zinc oxide liquid**
**LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25
 MEDIUM 7 - BEIGE- octinoxate and zinc oxide liquid**
**LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25
 OBSCURE 8 - BEIGE- octinoxate and zinc oxide liquid**
**LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25
 OBSCURE 9 - BEIGE- octinoxate and zinc oxide liquid**
**LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25 TONO
 HUT - BEIGE- octinoxate and zinc oxide liquid**
Ventura Corporation LTD

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.

L'BEL CONCENTRÉ TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
OCTINOXATE 7.0%	Sunscreen
ZINC OXIDE 7.2%	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.
- **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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

Other information

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

Inactive ingredients

DIMETHICONE, ALCOHOL DENAT., GLYCERIN, POLYSILICONE-11, MICA, PEG/PPG-18/18 DIMETHICONE, ZEA MAYS (CORN) STARCH, PEG-10 DIMETHICONE, BARIUM SULFATE, ALBIZIA JULIBRISSIN BARK EXTRACT, PHENOXYETHANOL, SILICA, METHYLPROPANEDIOL, TRIETHOXYCAPRYLYLSILANE, CAPRYLYL GLYCOL, CHLORPHENESIN, SILANEDIOL SALICYLATE, DISTEARDIMONIUM HECTORITE, TROMETHAMINE, CERAMIDE 3, FRAGRANCE, GRIFOLA FRONDOSA FRUITING BODY EXTRACT, MALTODEXTRIN, LINALOOL, d-LIMONENE, ALPHA-ISOMETHYL IONONE.

MAY CONTAIN:

TITANIUM DIOXIDE , IRON OXIDES.

Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926.

PRINCIPAL DISPLAY PANEL - 27 ml Bottle Box - CLAIRE 1- BEIGE**L'BEL**

CONCENTRÉ

TOTAL

BASE SÉRUM

ultra-fluid **foundation**

SPF 25

27 ml e (0.91 fl. oz.)



PRINCIPAL DISPLAY PANEL - 27 ml Bottle Box - CLAIRE 2- BEIGE

L'BEL

**CONCENTRÉ
TOTAL**

Drug Facts

Active Ingredients
 Octinoxate 7%
 Zinc Oxide 7.2%

Purpose
 Sunscreen
 Sunscreen

Uses
 ■ Helps prevent sunburn.

Warnings
 ■ **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
 ■ For external use only.

Drug Facts (continued)

■ 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.
 ■ Children under 6 months of age: Ask a doctor

Drug Facts (continued)

Other Information
 ■ Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Dimethicone, alcohol denat., glycerin, polyacrylate-1, mica, peg/ppg-18/18 dimethicone, zea mays (corn) starch, peg-10 dimethicone, butyl salicylate, albizia julibrissin bark extract, phenoxyethanol, silica, methylpropanediol, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, stearoyl salicylate, disteardimonium hectorite, trimethylamine, ceramide 3, fragrance, glicola triondesa fruiting body extract, maltodextrin, linoleol, d-limonene, alpha-isomethyl ionone, May contain: titanium dioxide, iron oxides.

U.S. Pat. Dec. by Vestant Br. Ltd. USA. Sellamp USA, Miami, FL 33176. Made in Colombia. PRODUCTO IMPORTADO. Dec. by Vestant Corp. Ltd., San Juan, Puerto Rico 00924. Made in Colombia

L'BEL

**CONCENTRÉ
TOTAL**

BASE SÉRUM
 base de maquillaje
 ultrafluida FPS 25
 ultra-fluid foundation
 SPF 25

27 ml e (0.91 fl. oz.)

BASE SÉRUM

ultra-fluid **foundation**
SPF 25

27 ml e (0.91 fl. oz.)



Drug Facts

Active Ingredients
Octinoxate 7%
Zinc Oxide 7.2%

Purpose
Sunscreen
Sunscreen

Uses
Helps prevent sunburn.

Warnings
Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
For external use only.

Drug Facts (continued)

- 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 8 months of age: Ask a doctor.

L'BEL

CONCENTRÉ
TOTAL

BASE SÉRUM
base de maquillage
ultrafluida FPS 25
ultra-fluid foundation
SPF 25

27 ml e (0.91 fl. oz.)

Drug Facts (continued)

Other Information

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

Inactive Ingredients Dimethicone, alcohol denat., glycerin, polyisobutene-1, mica, peg/ppg-18/18 dimethicone, zea mays (corn) starch, ppg-10 dimethicone, barium sulfate, albizia julibrissin bark extract, phenoxyethanol, silica, methylpropanediol, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, stannic dihydroxide, disearaonum hectorite, tosylamide, ceramide 3, fragrance, gilia frondosa fruiting body extract, maltodextrin, linoleol, d-limonene, alpha-terpineol, iron oxides.

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PRINCIPAL DISPLAY PANEL - 27 ml Bottle Box - CLAIRE 3- BEIGE

L'BEL

CONCENTRÉ

TOTAL

BASE SÉRUM

ultra-fluid **foundation**

SPF 25

27 ml e (0.91 fl. oz.)

BASE SÉRUM

ultra-fluid **foundation**
SPF 25

27 ml e (0.91 fl. oz.)



Drug Facts

Active Ingredients
Octinoxate 7%
Zinc Oxide 7.2%

Purpose
Sunscreen
Sunscreen

Uses
Helps prevent sunburn.

Warnings
Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
For external use only.

Drug Facts (continued)

- 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 8 months of age: Ask a doctor.

L'BEL

CONCENTRÉ
TOTAL

BASE SÉRUM
base de maquillage
ultrafluida FPS 25
ultra-fluid foundation
SPF 25

27 ml e (0.91 fl. oz.)

Drug Facts (continued)

Other Information

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

Inactive Ingredients Dimethicone, alcohol denat., glycerin, polydimethylsiloxane-11, mica, peg/ppg-18/18 dimethicone, zea mays (corn) starch, ppg-10 dimethicone, barium sulfate, albizia julibrissin bark extract, phenoxyethanol, silica, methylpropaneediol, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, stannic dihydroxyacetate, distearamonium hectorite, tromethamine, ceramide 3, fragrance, gilia frondosa fruiting body extract, maltodextrin, linoleol, d-limonene, alpha-terpineol, iron oxides.

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PRINCIPAL DISPLAY PANEL - 27 ml Bottle Box - MEDIUM 5- BEIGE

L'BEL

CONCENTRÉ

TOTAL

BASE SÉRUM

ultra-fluid **foundation**

SPF 25

27 ml e (0.91 fl. oz.)



PRINCIPAL DISPLAY PANEL - 27 ml Bottle Box - MEDIUM 6- BEIGE

L'BEL

**CONCENTRÉ
TOTAL**

Drug Facts

Active Ingredients
 Octinoxate 7%
 Zinc Oxide 7.2%

Purpose
 Sunscreen
 Sunscreen

Uses
 ■ Helps prevent sunburn.

Warnings
 ■ **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
 ■ For external use only.

Drug Facts (continued)

■ 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.
 ■ Children under 6 months of age: Ask a doctor

L'BEL

**CONCENTRÉ
TOTAL**

BASE SÉRUM
 base de maquillaje
 ultrafluida FPS 25
 ultra-fluid foundation
 SPF 25

27 ml e (0.91 fl. oz.)

Drug Facts (continued)

Other Information
 ■ Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Dimethicone, alcohol denat., glycerin, polyacrylate-11, mica, peg/ppg-18/18 dimethicone, zea mays (corn) starch, peg-10 dimethicone, butyl salicylate, albizia julibrissin bark extract, phenoxyethanol, silica, methylpropylmethacrylate, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, stearic acid calcium salt, disteardimonium hectorite, trimethylammonium ceramide 3, fragrance, glicola triondesa fruiting body extract, maltodextrin, linoleol, d-limonene, alpha-isomethyl ionone, May contain: titanium dioxide, iron oxides.

U.S. Pat. Dec. 27, 1994; by Vector, Inc. (USA) S&P Corp., Miami, FL 33176. Marca e Oloro de PATENTE M&CO, Inc. by Vector Corp., Ltd., San Juan, Puerto Rico 00924. Made in Colombia

BASE SÉRUM

ultra-fluid **foundation**
SPF 25

27 ml e (0.91 fl. oz.)



Drug Facts

Active Ingredients
Octinoxate 7%
Zinc Oxide 7.2%

Purpose
Sunscreen
Sunscreen

Uses
Helps prevent sunburn.

Warnings
Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
For external use only.

Drug Facts (continued)

- 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 8 months of age: Ask a doctor.

L'BEL

CONCENTRÉ
TOTAL

BASE SÉRUM
base de maquillage
ultrafluida FPS 25
ultra-fluid foundation
SPF 25

27 ml e (0.91 fl. oz.)

Drug Facts (continued)

Other Information

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

Inactive Ingredients Dimethicone, alcohol denat., glycerin, polyisobutene-1, mica, peg/ppg-18/18 dimethicone, zea mays (corn) starch, ppg-10 dimethicone, barium sulfate, albizia julibrissin bark extract, phenoxyethanol, silica, methylpropaneediol, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, stannic dihydroxide, disearaonum hectorite, tosylamide, ceramide 3, fragrance, gilia frondosa fruiting body extract, maltodextrin, inositol, d-limonene, alpha-terpineol, iron oxides.

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PRINCIPAL DISPLAY PANEL - 27 ml Bottle Box - MEDIUM 7- BEIGE

L'BEL

CONCENTRÉ

TOTAL

BASE SÉRUM

ultra-fluid **foundation**

SPF 25

27 ml e (0.91 fl. oz.)



PRINCIPAL DISPLAY PANEL - 27 ml Bottle Box - OBSCURE 8- BEIGE

L'BEL

**CONCENTRÉ
TOTAL**

Drug Facts

Active Ingredients
 Octinoxate 7%
 Zinc Oxide 7.2%

Purpose
 Sunscreen
 Sunscreen

Uses
 ■ Helps prevent sunburn.

Warnings
 ■ **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
 ■ For external use only.

Drug Facts (continued)

■ 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.
 ■ Children under 6 months of age: Ask a doctor.

Drug Facts (continued)

Other Information
 ■ Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Dimethicone, alcohol denat., glycerin, polyacrylate-11, mica, peg/ppg-18/18 dimethicone, zea mays (corn) starch, peg-10 dimethicone, butyl salicylate, albizia julibrissin bark extract, phenoxyethanol, silica, methylpropylmethacrylate, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, stearoyl salicylate, disteardimonium hectorite, trimethylammonium ceramide 3, fragrance, glicola triondesa, fruiting body extract, maltodextrin, linoleol, d-limonene, alpha-isomethyl ionone, May contain: titanium dioxide, iron oxides.

U.S. Lic. No. by Vector for L'Oréal Skincare USA, Miami, FL 33176. Made in Colombia. PRODUCTO IMPORTADO. Dist. by Vector Corp., LLC, San Juan, Puerto Rico 00924. Made in Colombia.

BASE SÉRUM

ultra-fluid **foundation**
SPF 25

27 ml e (0.91 fl. oz.)



Drug Facts

Active Ingredients
Octinoxate 7%
Zinc Oxide 7.2%

Purpose
Sunscreen
Sunscreen

Uses
Helps prevent sunburn.

Warnings
Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
For external use only.

Drug Facts (continued)

- 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 8 months of age: Ask a doctor.

L'BEL

CONCENTRÉ
TOTAL

BASE SÉRUM
base de maquillage
ultrafluida FPS 25
ultra-fluid foundation
SPF 25

27 ml e (0.91 fl. oz.)

Drug Facts (continued)

Other Information

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

Inactive Ingredients Dimethicone, alcohol denat., glycerin, polyisobutene-1, mica, peg/ppg-18/18 dimethicone, zea mays (corn) starch, ppg-10 dimethicone, barium sulfate, albizia julibrissin bark extract, phenoxyethanol, silica, methylpropanediol, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, stannic dihydroxide, disearaonum hectorite, tosylamide, ceramide 3, fragrance, gilia frondosa fruiting body extract, maltodextrin, linoleol, d-limonene, alpha-terpineol, iron oxides.

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PRINCIPAL DISPLAY PANEL - 27 ml Bottle Box - OBSCURE 9- BEIGE

L'BEL

CONCENTRÉ

TOTAL

BASE SÉRUM

ultra-fluid **foundation**

SPF 25

27 ml e (0.91 fl. oz.)



PRINCIPAL DISPLAY PANEL - 27 ml Bottle Box - TONO HUT- BEIGE

L'BEL

**CONCENTRÉ
TOTAL**

Drug Facts

Active Ingredients
 Octinoxate 7%
 Zinc Oxide 7.2%

Purpose
 Sunscreen
 Sunscreen

Uses
 ■ Helps prevent sunburn.

Warnings
 ■ **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
 ■ For external use only.

Drug Facts (continued)

■ 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions
 ■ Apply liberally and evenly 15 minutes before sun exposure.
 ■ Reapply at least every 2 hours.
 ■ Use a water resistant sunscreen if swimming or sweating.
 ■ Children under 6 months of age: Ask a doctor.

Drug Facts (continued)

Other Information
 ■ Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Dimethicone, alcohol denat., glycerin, polyacrylate-11, mica, peg/ppg-18/18 dimethicone, zea mays (corn) starch, peg-10 dimethicone, butyl salicylate, albizia julibrissin bark extract, phenoxyethanol, silica, methylpropanediol, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, stearoyl salicylate, disteardimonium hectorite, trimethylammonium ceramide 3, fragrance, glicola triondesa, fruiting body extract, maltodextrin, linoleol, d-limonene, alpha-isomethyl ionone, May contain: titanium dioxide, iron oxides.

U.S. Pat. Dec. by Vestant Br. Ltd. USA. Sellamp USA, Miami, FL 33176. Made in Colombia. PRODUCTO HECHO EN COLOMBIA. Distribuido por Vestant Corp., Inc., San Juan, Puerto Rico 00924, Made in Colombia.

BASE SÉRUM

ultra-fluid **foundation**
SPF 25

27 ml e (0.91 fl. oz.)



Drug Facts

Active Ingredients
Octinoxate 7%
Zinc Oxide 7.2%

Purpose
Sunscreen
Sunscreen

Uses
Helps prevent sunburn.

Warnings
Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
For external use only.

Drug Facts (continued)

- 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 8 months of age: Ask a doctor.

L'BEL

CONCENTRÉ
TOTAL

BASE SÉRUM
base de maquillage
ultrafluida FPS 25
ultra-fluid foundation
SPF 25

27 ml e (0.91 fl. oz.)

Drug Facts (continued)

Other Information

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

Inactive Ingredients Dimethicone, alcohol denat., glycerin, polyisobutene-1, mica, peg/ppg-18/18 dimethicone, zea mays (corn) starch, ppg-70 dimethicone, barium sulfate, abies balsamea bark extract, phenoxyethanol, silica, methylpropanediol, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, stannic dihydroxyacetate, distearamonium hectorite, tromethamine, ceramide 3, fragrance, gilia frondosa fruiting body extract, maltodextrin, linoleol, d-limonene, alpha-terpineol, iron oxides.

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LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25 CLAIRE 1 - BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0038
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.072 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
MICA (UNII: V8A1AW0880)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
STARCH, CORN (UNII: O8232NY3SJ)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
ALBIZIA JULIBRISSIN BARK (UNII: 0J9G6W44DV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TROMETHAMINE (UNII: 023C2WHX2V)	
CERAMIDE NP (UNII: 4370DF050B)	
MAITAKE (UNII: A1U5YJIOZ8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0038-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0038-1	27 mL in 1 BOTTLE, PLASTIC; 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	01/27/2017	

LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25 CLAIRE 2 - BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0039
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.072 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
MICA (UNII: V8A1AW0880)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
STARCH, CORN (UNII: O8232NY3SJ)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
ALBIZIA JULIBRISSIN BARK (UNII: 0J9G6W44DV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	

DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)

TROMETHAMINE (UNII: 023C2WHX2V)

CERAMIDE NP (UNII: 4370DF050B)

MAITAKE (UNII: A1U5YJI0Z8)

MALTODEXTRIN (UNII: 7CVR7L4A2D)

LINALOOL, (+/-)- (UNII: D81QY6I88E)

LIMONENE, (+)- (UNII: GFD7C86Q1W)

ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0039-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0039-1	27 mL in 1 BOTTLE, PLASTIC; 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	01/27/2017	

LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25 CLAIRE 3 - BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.072 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	

MICA (UNII: V8A1AW0880)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
STARCH, CORN (UNII: O8232NY3SJ)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
BARIUM SULFATE (UNII: 25BB7EKE2E)
ALBIZIA JULIBRISSIN BARK (UNII: 0J9G6W44DV)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
TROMETHAMINE (UNII: 023C2WHX2V)
CERAMIDE NP (UNII: 4370DF050B)
MAITAKE (UNII: A1U5YJ10Z8)
MALTO DEXTRIN (UNII: 7CVR7L4A2D)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0040-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0040-1	27 mL in 1 BOTTLE, PLASTIC; 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	01/27/2017	

LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25 CLAIRE 4 - BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0041
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.072 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
MICA (UNII: V8A1AW0880)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
STARCH, CORN (UNII: O8232NY3SJ)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
ALBIZIA JULIBRISSIN BARK (UNII: 0J9G6W44DV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
TRIETHOXYCAPRYL YLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TROMETHAMINE (UNII: 023C2WHX2V)	
CERAMIDE NP (UNII: 4370DF050B)	
MAITAKE (UNII: A1U5YJI0Z8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0041-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0041-1	27 mL in 1 BOTTLE, PLASTIC; 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	01/27/2017	

LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25 MEDIUM 5 - BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0042
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.072 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
MICA (UNII: V8A1AW0880)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
STARCH, CORN (UNII: O8232NY3SJ)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
ALBIZIA JULIBRISSIN BARK (UNII: 0J9G6W44DV)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TROMETHAMINE (UNII: 023C2WHX2V)	
CERAMIDE NP (UNII: 4370DF050B)	
MAITAKE (UNII: A1U5YJI0Z8)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0042-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0042-1	27 mL in 1 BOTTLE, PLASTIC; 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	01/27/2017	

LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25 MEDIUM 6 - BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0043
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.072 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
MICA (UNII: V8A1AW0880)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
STARCH, CORN (UNII: O8232NY3SJ)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
ALBIZIA JULIBRISSIN BARK (UNII: 0J9G6W44DV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	

DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)

TROMETHAMINE (UNII: 023C2WHX2V)

CERAMIDE NP (UNII: 4370DF050B)

MAITAKE (UNII: A1U5YJI0Z8)

MALTODEXTRIN (UNII: 7CVR7L4A2D)

LINALOOL, (+/-)- (UNII: D81QY6I88E)

LIMONENE, (+)- (UNII: GFD7C86Q1W)

ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0043-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0043-1	27 mL in 1 BOTTLE, PLASTIC; 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	01/27/2017	

LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25 MEDIUM 7 - BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0044
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.072 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	

MICA (UNII: V8A1AW0880)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
STARCH, CORN (UNII: O8232NY3SJ)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
BARIUM SULFATE (UNII: 25BB7EKE2E)
ALBIZIA JULIBRISSIN BARK (UNII: 0J9G6W44DV)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
TROMETHAMINE (UNII: 023C2WHX2V)
CERAMIDE NP (UNII: 4370DF050B)
MAITAKE (UNII: A1U5YJ10Z8)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0044-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0044-1	27 mL in 1 BOTTLE, PLASTIC; 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	01/27/2017	

LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25 OBSCURE 8 - BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0045
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.072 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
MICA (UNII: V8A1AW0880)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
STARCH, CORN (UNII: O8232NY3SJ)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
ALBIZIA JULIBRISSIN BARK (UNII: 0J9G6W44DV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
TRIETHOXYCAPRYL YLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TROMETHAMINE (UNII: 023C2WHX2V)	
CERAMIDE NP (UNII: 4370DF050B)	
MAITAKE (UNII: A1U5YJI0Z8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0045-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0045-1	27 mL in 1 BOTTLE, PLASTIC; 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	01/27/2017	

LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25 OBSCURE 9 - BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0046
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.072 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
MICA (UNII: V8A1AW0880)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
STARCH, CORN (UNII: O8232NY3SJ)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
ALBIZIA JULIBRISSIN BARK (UNII: 0J9G6W44DV)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TROMETHAMINE (UNII: 023C2WHX2V)	
CERAMIDE NP (UNII: 4370DF050B)	
MAITAKE (UNII: A1U5YJI0Z8)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0046-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0046-1	27 mL in 1 BOTTLE, PLASTIC; 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	01/27/2017	

LBEL CONCENTRE TOTAL BASE SERUM ULTRA-FLUID FOUNDATION SPF 25 TONO HUT - BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0047
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.072 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
MICA (UNII: V8A1AW0880)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
STARCH, CORN (UNII: O8232NY3SJ)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
ALBIZIA JULIBRISSIN BARK (UNII: 0J9G6W44DV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	

DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
TROMETHAMINE (UNII: 023C2WHX2V)
CERAMIDE NP (UNII: 4370DF050B)
MAITAKE (UNII: A1U5YJI0Z8)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0047-2	1 in 1 BOX	01/27/2017	
1	NDC:43596-0047-1	27 mL in 1 BOTTLE, PLASTIC; 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	01/27/2017	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(43596-0038, 43596-0039, 43596-0040, 43596-0041, 43596-0042, 43596-0043, 43596-0044, 43596-0045, 43596-0046, 43596-0047)

Revised: 11/2019

Ventura Corporation LTD