

**LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO
FPS 15 LONG LASTING COMPACT SPF 15 (CLAIRE 1) - BEIGE- titanium dioxide and zinc
oxide powder**

**LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO
FPS 15 LONG LASTING COMPACT SPF 15 (CLAIRE 2) - BEIGE- titanium dioxide and zinc
oxide powder**

**LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO
FPS 15 LONG LASTING COMPACT SPF 15 (CLAIRE 3) - BEIGE- titanium dioxide and zinc
oxide powder**

**LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO
FPS 15 LONG LASTING COMPACT SPF 15 (CLAIRE 4) - BEIGE- titanium dioxide and zinc
oxide powder**

**LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO
FPS 15 LONG LASTING COMPACT SPF 15 (MEDIUM 5) - BEIGE- titanium dioxide and zinc
oxide powder**

**LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO
FPS 15 LONG LASTING COMPACT SPF 15 (MEDIUM 6) - BEIGE- titanium dioxide and zinc
oxide powder**

**LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO
FPS 15 LONG LASTING COMPACT SPF 15 (MEDIUM 7) - BEIGE- titanium dioxide and zinc
oxide powder**

**LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO
FPS 15 LONG LASTING COMPACT SPF 15 (OBSCURE 8) - BROWN- titanium dioxide and
zinc oxide powder**

**LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO
FPS 15 LONG LASTING COMPACT SPF 15 (OBSCURE 9) - BROWN- titanium dioxide and
zinc oxide powder**

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 EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACIÓN PARA ROSTRO
FPS 15 LONG LASTING COMPACT POWDER SPF 15.**

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
TITANIUM DIOXIDE 5.7525 %	Sunscreen
ZINC OXIDE 4.90 %	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

MICA, DIMETHICONE, POLYMETHYLSILSESQUIOXANE, ZINC STEARATE, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, TRIMETHYLSILOXYSILICATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, PERFLUOROCTYL TRIETHOXYSILANE, TOCOPHERYL ACETATE, HYDROGEN DIMETHICONE, PHENOXYETHANOL, CETYL PEG/PPG-10/1 DIMETHICONE, POLYGLYCERYL-4 ISOSTEARATE, ALUMINA, HEXYL LAURATE, FRAGRANCE, CAPRYLYL GLYCOL, CRITHMUM MARITIMUM EXTRACT, TRIETHOXYCAPRYLYLSILANE, CHLORPHENESIN, CERAMIDE 3, BUTYLPHENYL METHYLPROPIONAL, HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE, HYDROXYCITRONELLAL, CITRONELLOL, GERANIOL, d-LIMONENE, ALPHA-ISOMETHYL IONONE.

MAY CONTAIN: IRON OXIDES, TITANIUM DIOXIDE.

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

PRINCIPAL DISPLAY PANEL - 12 g Case Box - (CLAIRE 1) - BEIGE

L'BEL

EFFET PARFAIT

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)



PRINCIPAL DISPLAY PANEL - 12 g Case Box - (CLAIRE 2) - BEIGE

L'BEL

EFFET PARFAIT

long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)



PRINCIPAL DISPLAY PANEL - 12 g Case Box - (CLAIRE 3) - BEIGE

L'BEL

EFFET PARFAIT

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)



L'BEL

EFFET PARFAIT

polvos compactos de larga duración para rostro **FPS 15**

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)

Drug Facts

Active Ingredients
Titanium dioxide 5.7%
Zinc oxide 4.9%
Sunscreen

Purpose
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.

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

Inactive ingredients
mica, dimethicone, polymethylsiloxane, zinc stearate, hdlttrimethylol hexyllactate, crosspolymer, trimethylsiloxyethylacetate, caprylic/capric triglyceride, perfume, hydroxyethylacetate, tocopherol acetate, hydrogen dimethicone, phenylethanol, cetyl ppg-10/1 dimethicone, polyglyceryl-4 isostearate, alumina, hexyl laurate, fragrance, caprylyl glycol, cithium maritimum extract, triethoxycaprylylsilane, chlorophenol, ceramide 3, butylphenyl methylpropional, hydroxyisohexyl 3-cylohexene carboxaldehyde, hydroxy citronellal, citronellol, geraniol, limonene, alpha-isomethyl ionone. May contain: iron oxides, titanium dioxide.

U.S.A.: Owned by Ventura Parfait, DBA Belcorp USA, Miami, FL 33126. Made in Colombia. PUERTO RICO: Owned by Ventura Corp. Ltd., San Juan, Puerto Rico 00926. Made in Colombia. www.lbel.com

PRINCIPAL DISPLAY PANEL - 12 g Case Box - (CLAIRE 4) - BEIGE

L'BEL

EFFET PARFAIT

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)



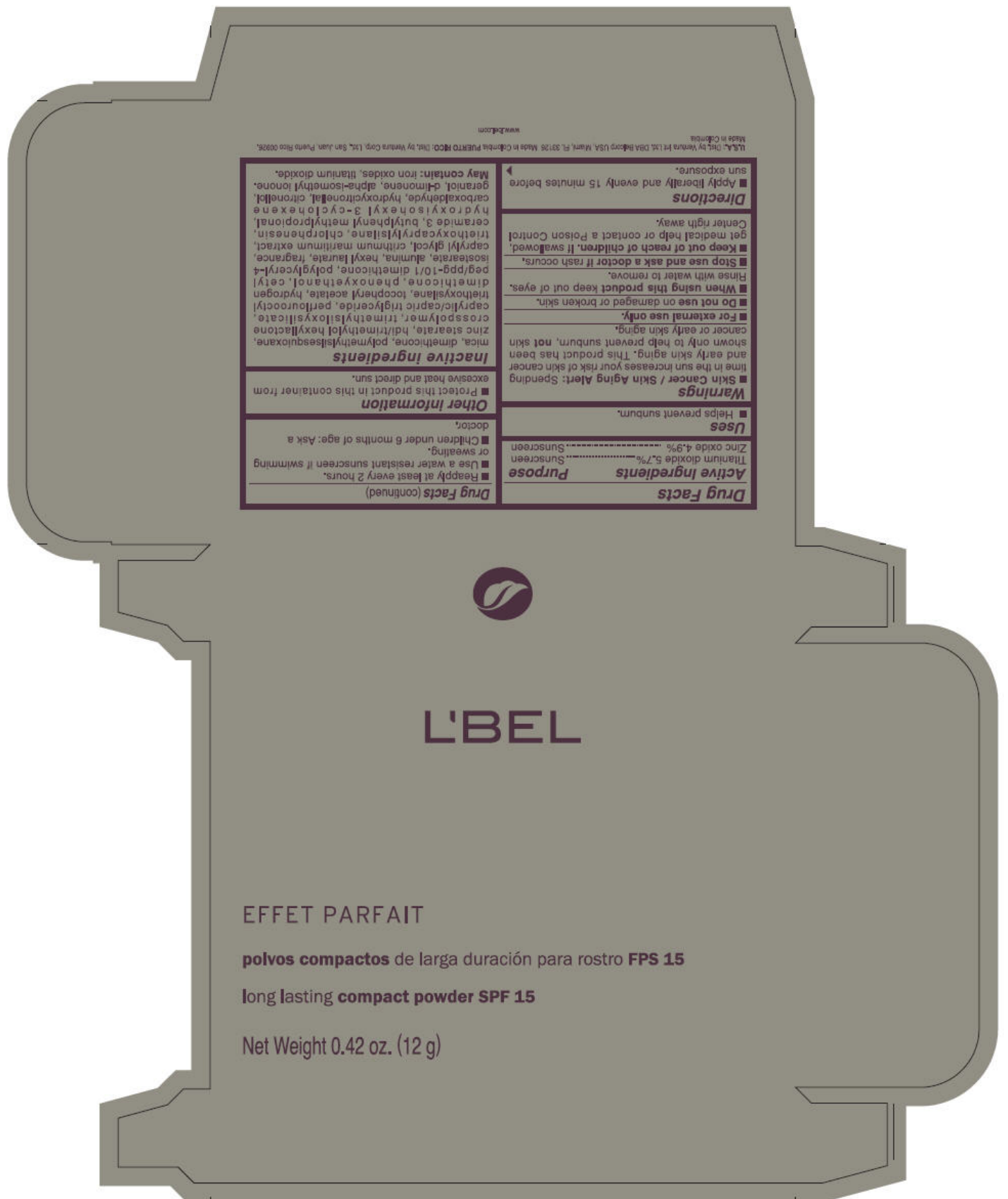
PRINCIPAL DISPLAY PANEL - 12 g Case Box - (MEDIUM 5) - BEIGE

L'BEL

EFFET PARFAIT

long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)



PRINCIPAL DISPLAY PANEL - 12 g Case Box - (MEDIUM 6) - BEIGE

L'BEL

EFFET PARFAIT

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)



L'BEL

EFFET PARFAIT

polvos compactos de larga duración para rostro **FPS 15**

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)

Drug Facts (continued)

■ Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating.

■ Children under 6 months of age: Ask a doctor.

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

Inactive ingredients
 mica, dimethicone, polymethylsiloxane, zinc stearate, hdlttrimethylol hexyllactate, crosspolymer, trimethylsiloxyethylacetate, caprylic/capric triglyceride, perfume, hydroxyethylacetate, phenylethanol, cetyl dimethicone, polyglyceryl-4-isostearate, alumina, hexyl laurate, fragrance, caprylyl glycol, cithium maritimum extract, triethoxycaprylylsilane, chlorophenol, ceramide 3, butylphenyl methylpropional, hydroxyisohexyl 3-cylohexene carboxaldehyde, hydroxycitronellal, citronellol, geraniol, limonene, alpha-isomethyl ionone. May contain: iron oxides, titanium dioxide.

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.

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PRINCIPAL DISPLAY PANEL - 12 g Case Box - (MEDIUM 7) - BEIGE

L'BEL

EFFET PARFAIT

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)



PRINCIPAL DISPLAY PANEL - 12 g Case Box - (OBSCURE 8) - BROWN

L'BEL

EFFET PARFAIT

long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)



PRINCIPAL DISPLAY PANEL - 12 g Case Box - (OBSCURE 9) - BROWN

L'BEL

EFFET PARFAIT

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)



L'BEL

EFFET PARFAIT

polvos compactos de larga duración para rostro **FPS 15**

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)

Drug Facts

Active Ingredients

Titanium dioxide 5.7%
Zinc oxide 4.9%

Purpose

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.

May contain: iron oxides, titanium dioxide, geraniol, d-limonene, alpha-isomethyl ionone, carbokaldehyde, hydroxycitronellal, citronellol, hydroxyisohexyl 3-cyclohexene ceramide 3, butylphenyl methylpropional, triethoxycaprylylsilane, chlorophenol, caprylyl glycol, cithium maritimum extract, isostearate, alumina, hexyl laurate, fragrance, peg/ppg-10/1 dimethicone, polyglyceryl-4 dimethicone, phenylethanol, cetyl triethoxysilane, tocopherol acetate, hydrogen caprylic/capric triglyceride, perfume/cosmopolymer, trimethylsiloxyethylacetate, zinc stearate, hd/trimethylol hexyllactone, mica, dimethicone, polymethylsilsesquioxane.

Inactive ingredients

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

Other Information

For external use only. Ask a doctor if you are pregnant, nursing, or taking other medications.

Children under 6 months of age: Ask a doctor.

Drug Facts (continued)

U.S.A.: Owned by Ventura Parfait, DBA Belcorp USA, Miami, FL 33126. Made in Colombia. PUERTO RICO: Owned by Ventura Corp. Ltd., San Juan, Puerto Rico 00926. Made in Colombia. www.lbel.com

LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO FPS 15 LONG LASTING COMPACT SPF 15 (CLAIRE 1) - BEIGE

titanium dioxide and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-991
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.057 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISO CYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-991-02	1 in 1 BOX	08/17/2015	
1	NDC:13537-991-01	12 g in 1 CASE; 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	08/17/2015	

LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO FPS 15 LONG LASTING COMPACT SPF 15 (CLAIRE 2) - BEIGE

titanium dioxide and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-992
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.057 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISO CYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-992-02	1 in 1 BOX	08/17/2015	
1	NDC:13537-992-01	12 g in 1 CASE; 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	08/17/2015	

LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO FPS 15 LONG LASTING COMPACT SPF 15 (CLAIRE 3) - BEIGE

titanium dioxide and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-237
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.057 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y10)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISO CYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISO STEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	

.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-237-02	1 in 1 BOX	08/17/2015	
1	NDC:13537-237-01	12 g in 1 CASE; 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	08/17/2015	

LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO FPS 15 LONG LASTING COMPACT SPF 15 (CLAIRE 4) - BEIGE

titanium dioxide and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-238
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.057 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISO CYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	

TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
GERANIOL (UNII: L837108USY)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-238-02	1 in 1 BOX	08/17/2015	
1	NDC:13537-238-01	12 g in 1 CASE; 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	08/17/2015	

LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO FPS 15 LONG LASTING COMPACT SPF 15 (MEDIUM 5) - BEIGE

titanium dioxide and zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-239
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.057 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISO CYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
ALUMINUM OXIDE (UNII: LM26O6933)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
GERANIOL (UNII: L837108USY)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-239-02	1 in 1 BOX	08/17/2015	
1	NDC:13537-239-01	12 g in 1 CASE; 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	08/17/2015	

LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO FPS 15 LONG LASTING COMPACT SPF 15 (MEDIUM 6) - BEIGE
titanium dioxide and zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-702
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.057 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-702-02	1 in 1 BOX	08/17/2015	
1	NDC:13537-702-01	12 g in 1 CASE; 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	08/17/2015	

LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO FPS 15 LONG LASTING COMPACT SPF 15 (MEDIUM 7) - BEIGE

titanium dioxide and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-748
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.057 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-748-02	1 in 1 BOX	08/17/2015	
1	NDC:13537-748-01	12 g in 1 CASE; 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	08/17/2015	

LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO FPS 15 LONG LASTING COMPACT SPF 15 (OBSCURE 8) - BROWN
titanium dioxide and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-749
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.057 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISO CYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-749-02	1 in 1 BOX	08/17/2015	
1	NDC:13537-749-01	12 g in 1 CASE; 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	08/17/2015	

LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO FPS 15 LONG LASTING COMPACT SPF 15 (OBSCURE 9) - BROWN

titanium dioxide and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-750
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.057 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISO CYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-750-02	1 in 1 BOX	08/17/2015	
1	NDC:13537-750-01	12 g in 1 CASE; 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	08/17/2015	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-991, 13537-992, 13537-237, 13537-238, 13537-239, 13537-702, 13537-748, 13537-749, 13537-750)

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Ventura Corporation LTD