

**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 International 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 Int Ltd. DBA Belcorp USA, Miami, FL 33126

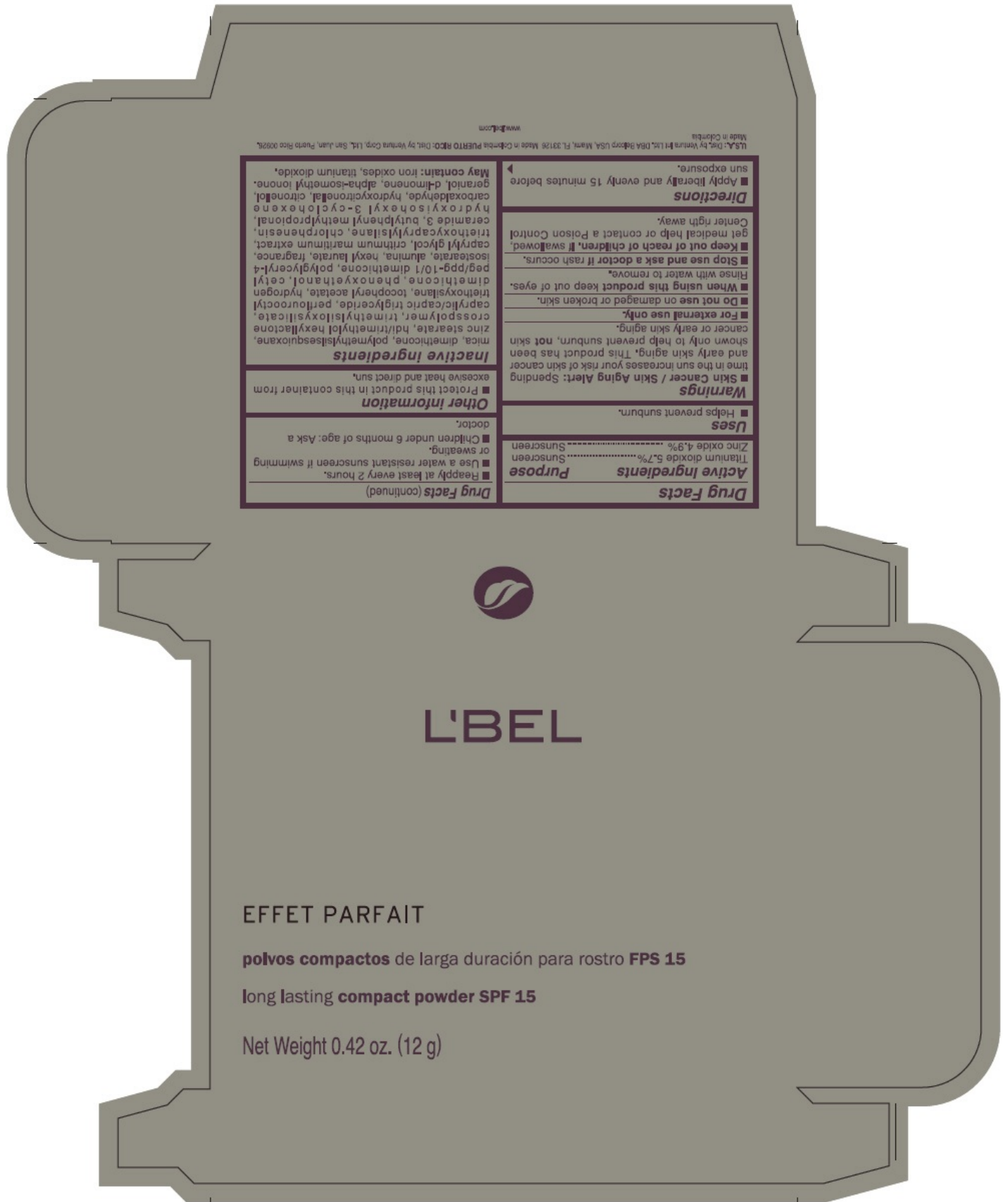
PRINCIPAL DISPLAY PANEL - 12 g Case Box - (CLAIRE 1) - BEIGE

L'BEL

EFFET PARFAIT

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)



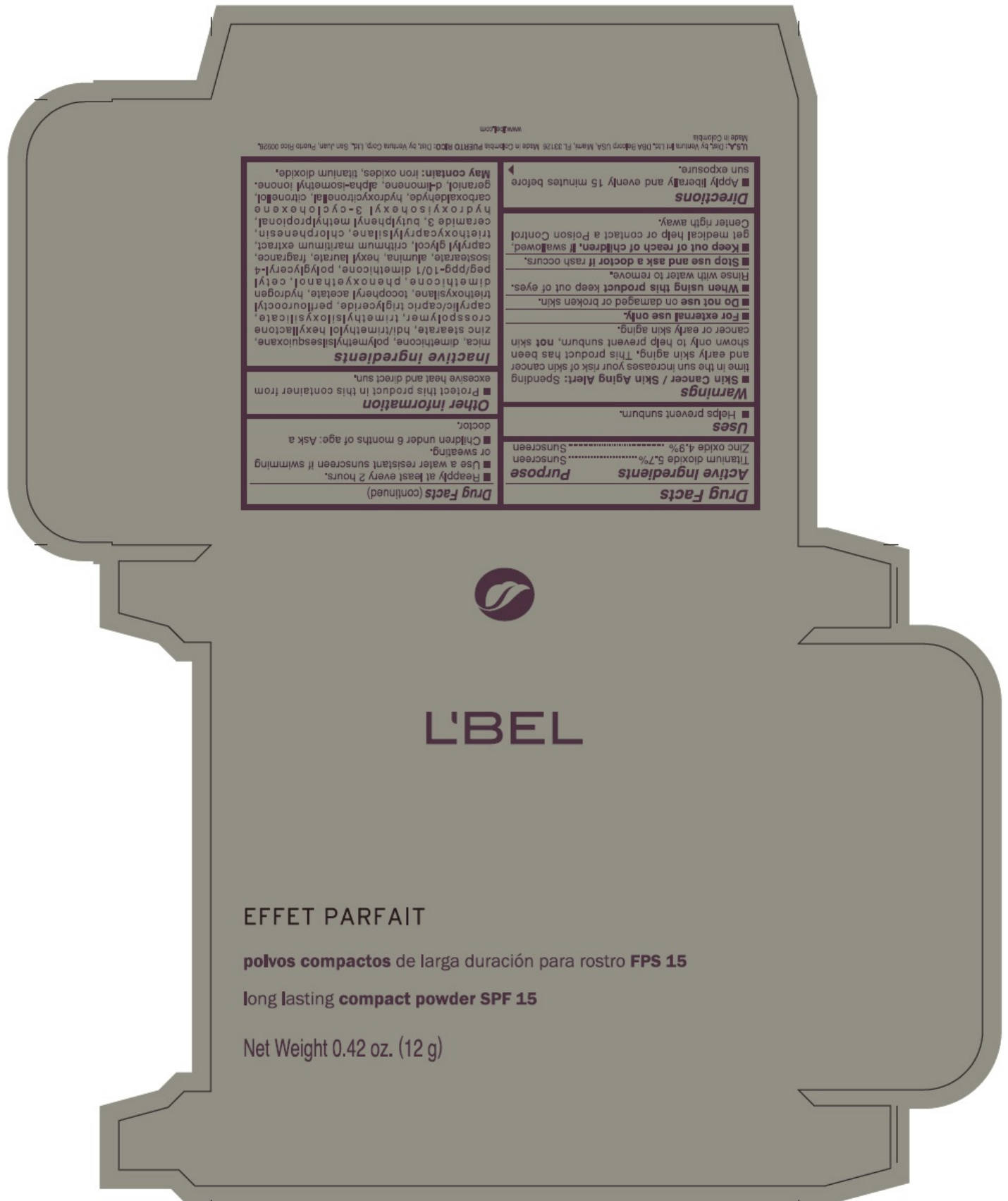
PRINCIPAL DISPLAY PANEL - 12 g Case Box - (CLAIRE 2) - BEIGE

L'BEL

EFFET PARFAIT

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)



USA: Dist. by Venura Int'l, Inc., DBA Adcorp USA, Miami, FL 33176. Made in Colombia. PUERTO RICO: Dist. by Venura Corp. Ltd., San Juan, Puerto Rico 00926. www.lbel.com

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.
Do not use on damaged or broken skin.
For external use only.

Directions
Apply liberally and evenly 15 minutes before sun exposure.
Center right away.

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

Inactive ingredients
mica, dimethicone, polyethylsiloxane, zinc stearate, hd/trimethylol hexyllactate, crosspolymer, trimethylsiloxysilicate, triethoxysilane, tocopheryl acetate, hydrogen dimethicone, phenoxyethanol, cetyl ppg-10/1 dimethicone, polyglyceryl-4-isostearate, alumina, hexyl laurate, fragrance, ceramide 3, butylphenyl methylpropional, triethoxycaprylylsilane, chlorophenol, ceramide 3, butylphenyl methylpropional, hydroxyisohexyl 3-cyclohexenecarboxaldehyde, alpha-isomethyl ionone, geraniol, d-limonene, alpha-somethyl ionone, carbocadehyde, hydroxycitronellal, citronellol.

May contain: iron oxides, titanium dioxide.

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.



L'BEL

EFFET PARFAIT

polvos compactos de larga duración para rostro FPS 15

long lasting **compact powder SPF 15**

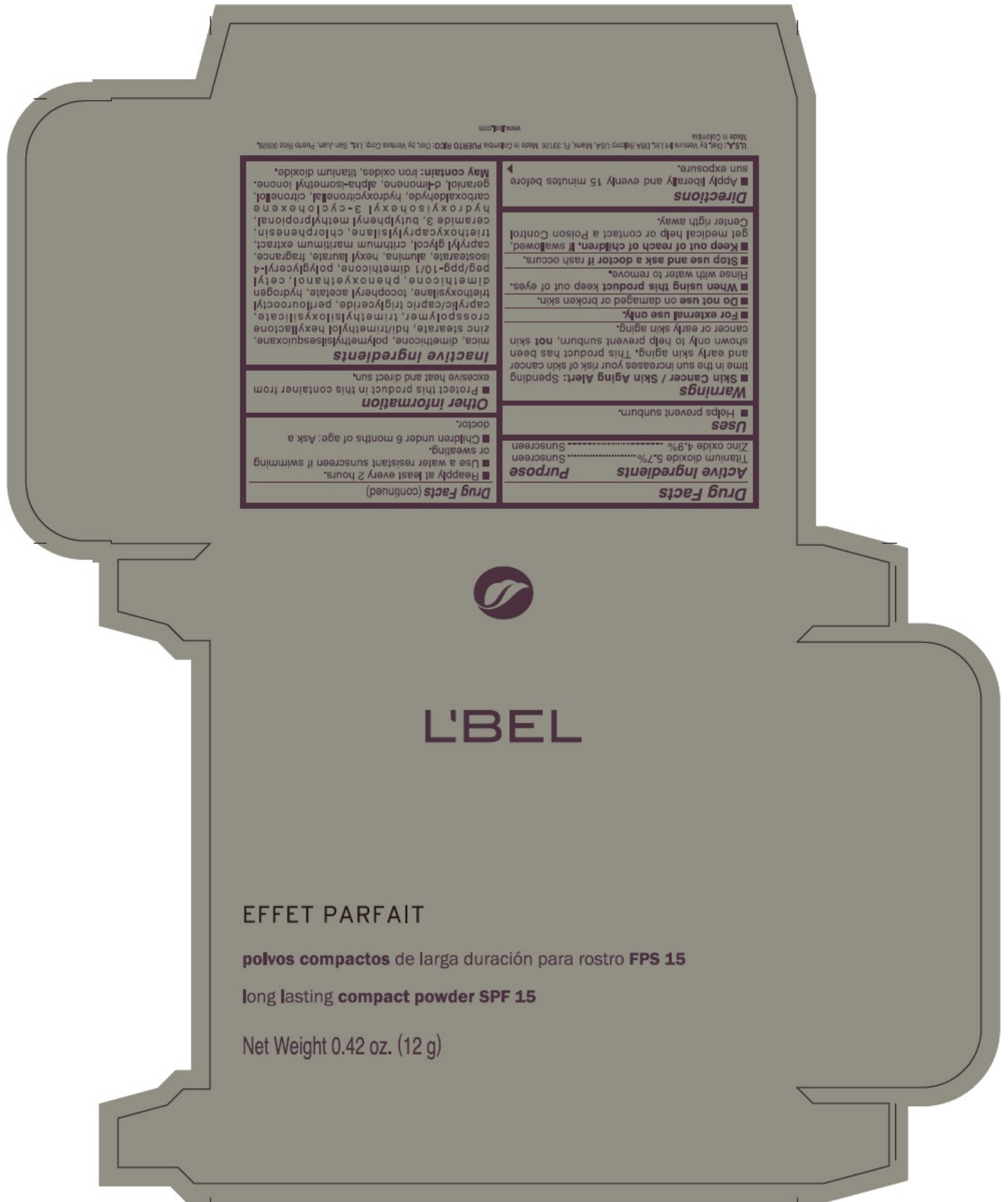
Net Weight 0.42 oz. (12 g)

L'BEL

EFFET PARFAIT

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)



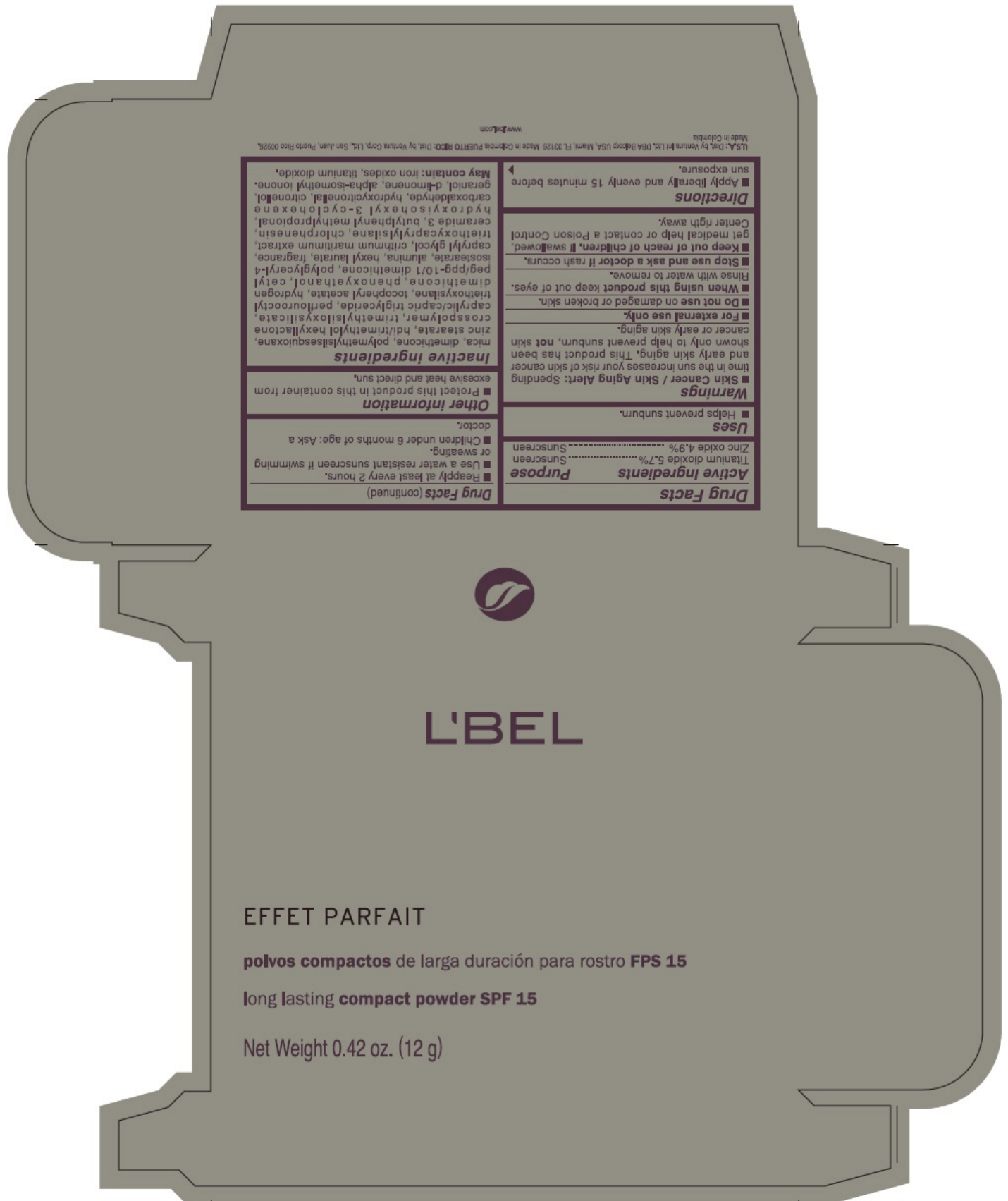
PRINCIPAL DISPLAY PANEL - 12 g Case Box - (CLAIRE 4) - BEIGE

L'BEL

EFFET PARFAIT

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)



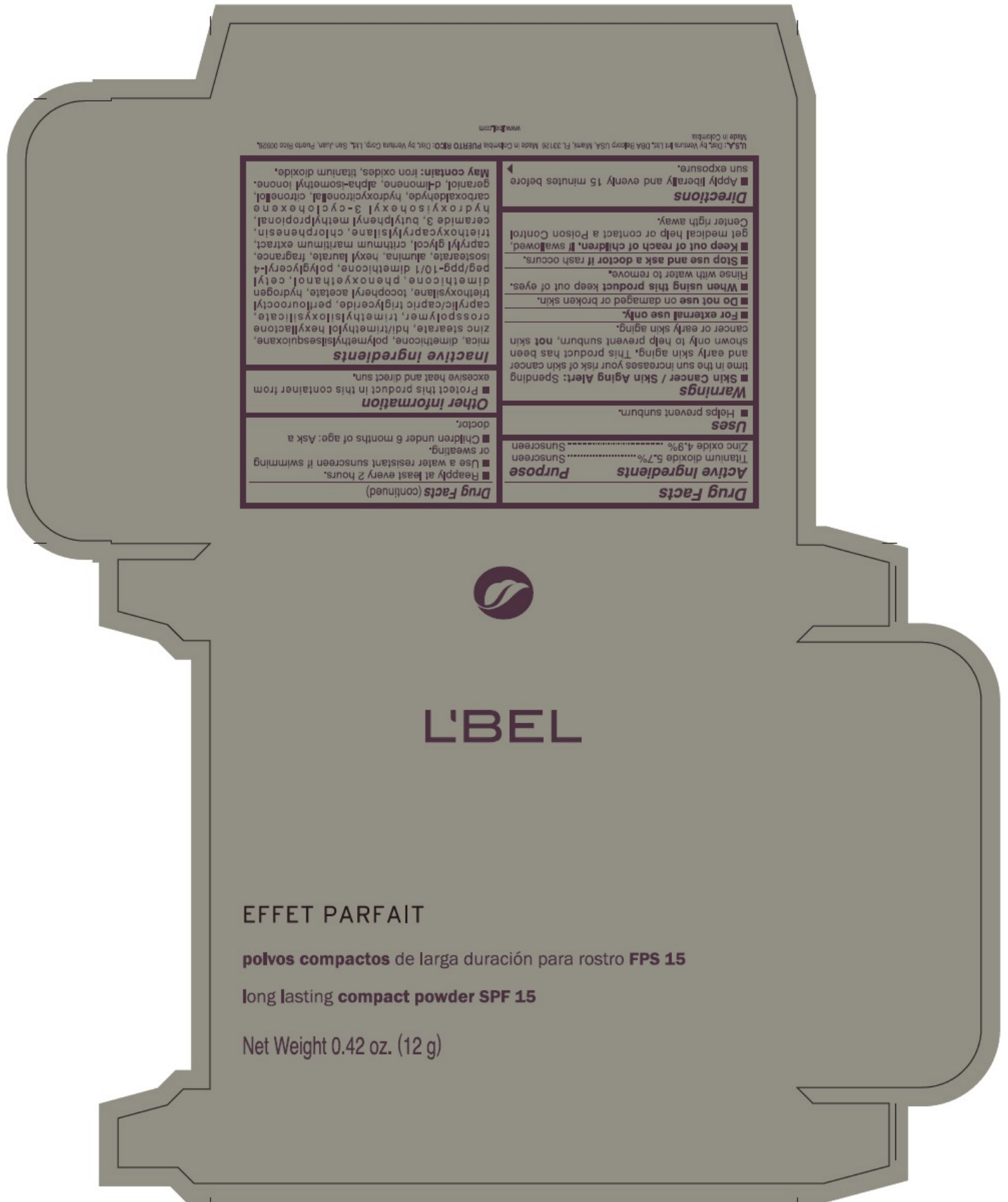
PRINCIPAL DISPLAY PANEL - 12 g Case Box - (MEDIUM 5) - BEIGE

L'BEL

EFFET PARFAIT

long lasting **compact powder SPF 15**

Net Weight 0.42 oz. (12 g)



Drug Facts

Active Ingredients
Titanium dioxide 5.7%
Zinc oxide 4.9%
Sunscreen

Purpose
■ Reapply at least every 2 hours.
■ Use a water resistant sunscreen if swimming or sweating.
■ Children under 6 months of age: Ask a doctor.

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, carboxaldehyde, hydroxyacetone, citronellol, hydroxyisohexyl 3-cyclohexene ceramide 3, butylphenyl methylpropional, triethoxycaprylylsilane, chlorophenol, caprylyl glycol, crithmum maritimum extract, isostearate, alumina, hexyl laurate, fragrance, peg/ppg-10/1 dimethicone, polyglyceryl-4-dimethicone, phenoxethanol, cetyl triethoxysilane, tocopheryl acetate, hydrogen caprylic/capric triglyceride, perfluorocetyl crosspolymer, trimethylsilyloxyethyl zinc stearate, hdtrimethylol hexyllactone, mica, dimethicone, polymethylsilsesquioxane.

Inactive ingredients

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

Drug Facts (continued)

Other information
■ Reapply at least every 2 hours.
■ Use a water resistant sunscreen if swimming or sweating.
■ Children under 6 months of age: Ask a doctor.

USA: Dist. by Veneta LLC, DBA Adcorp USA, Miami, FL 33126. Made in Colombia. **PUERTO RICO:** Dist. by Veneta Corp. Ltd., San Juan, Puerto Rico 00926. www.lbel.com



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)

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)



USA: Dist. by Ventura Int'l, DBA Adcorp USA, Miami, FL 33126. Made in Colombia. PUERTO RICO: Dist. by Ventura Corp. Ltd., San Juan, Puerto Rico 00926. www.lbel.com

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.
Do not use on damaged or broken skin.
For external use only.

Directions
Apply liberally and evenly 15 minutes before sun exposure.
Center right away.

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

Inactive ingredients
mica, dimethicone, polyethylsiloxane, zinc stearate, hd/trimethylol hexyllactate, crosspolymer, trimethylsiloxysilicate, triethoxysilane, tocopheryl acetate, hydrogen dimethicone, phenoxyethanol, cetyl ppg-10/1 dimethicone, polyglyceryl-4-isostearate, alumina, hexyl laurate, fragrance, ceramide 3, butylphenyl methylpropional, triethoxycaprylylsilane, chlorophenol, ceramide 3, butylphenyl methylpropional, hydroxyisohexyl 3-cyclohexenecarboxaldehyde, alpha-isomethyl ionone, geraniol, d-limonene, alpha-somethyl ionone.

May contain: iron oxides, titanium dioxide.

Drug Facts (continued)
Apply 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

EFFET PARFAIT

polvos compactos de larga duración para rostro FPS 15

long lasting **compact powder SPF 15**

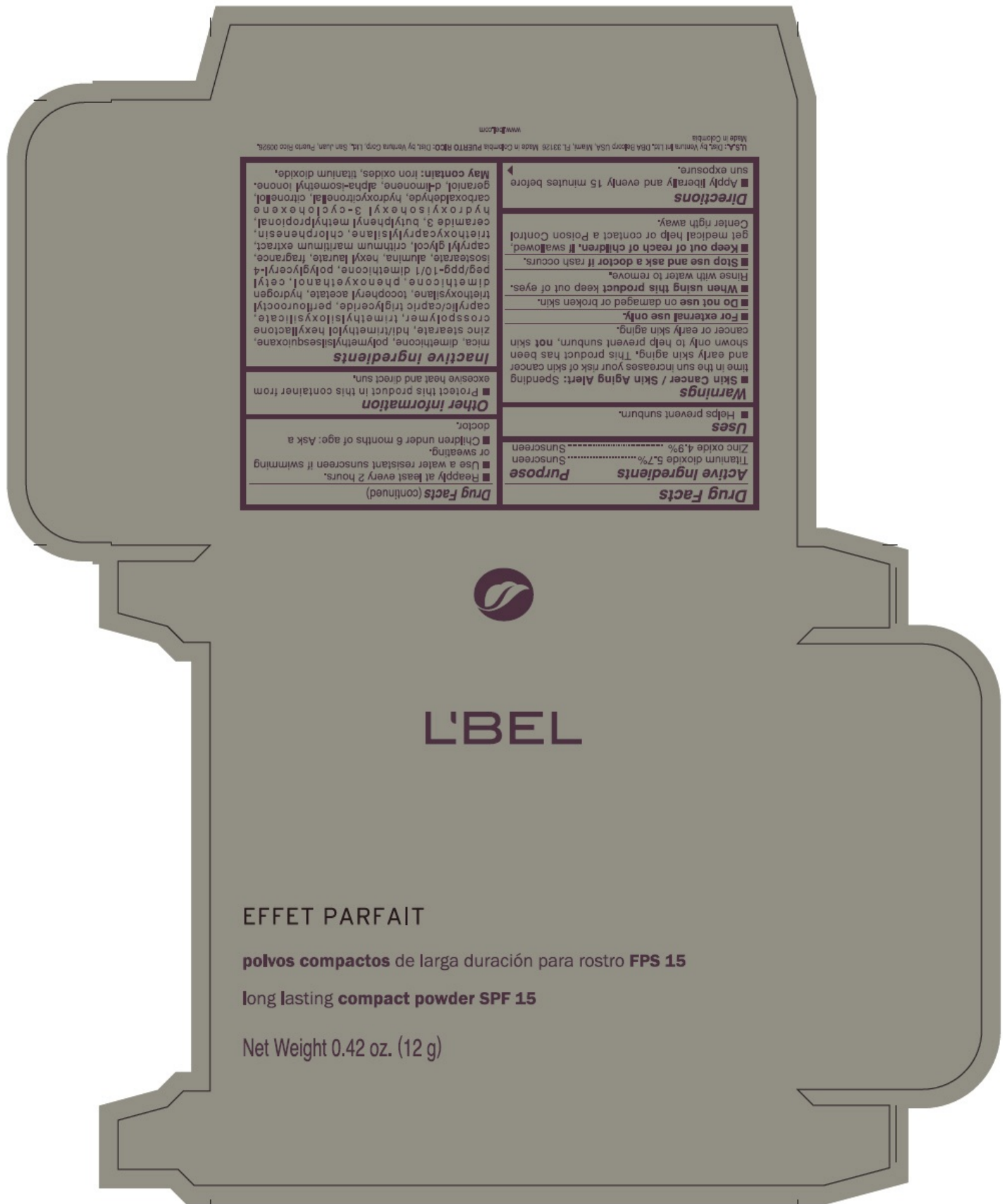
Net Weight 0.42 oz. (12 g)

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)

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-956
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)	
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:14783-956-02	1 in 1 BOX	08/18/2015	
1	NDC:14783-956-01	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	08/18/2015	

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:14783-957
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:14783-957-02	1 in 1 BOX	08/18/2015	
1	NDC:14783-957-01	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	08/18/2015	

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:14783-958
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:14783-958-02	1 in 1 BOX	08/18/2015	
1	NDC:14783-958-01	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	08/18/2015	

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:14783-959
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:14783-959-02	1 in 1 BOX	08/18/2015	
1	NDC:14783-959-01	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	08/18/2015	

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:14783-960
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:14783-960-02	1 in 1 BOX	08/18/2015	
1	NDC:14783-960-01	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	08/18/2015	

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:14783-961
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: HE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
ALUMINUM OXIDE (UNII: LM26O6933)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CRITHMUM MARITIMUM (UNII: J7HY79BKY)
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:14783-961-02	1 in 1 BOX	08/18/2015	
1	NDC:14783-961-01	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	08/18/2015	

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:14783-962
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)	
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:14783-962-02	1 in 1 BOX	08/18/2015	
1	NDC:14783-962-01	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	08/18/2015	

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:14783-963
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:14783-963-02	1 in 1 BOX	08/18/2015	
1	NDC:14783-963-01	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	08/18/2015	

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:14783-964
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:14783-964-02	1 in 1 BOX	08/18/2015	
1	NDC:14783-964-01	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	08/18/2015	

Labeler - Ventura International LTD (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-956, 14783-957, 14783-958, 14783-959, 14783-960, 14783-961, 14783-962, 14783-963, 14783-964)

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Ventura International LTD