

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

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

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

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

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

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

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

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

**LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO
FPS 15 /LONG LASTING COMPACT SPF 15 (OBSCURE 9) - BROWN- zinc oxide and titanium
dioxide 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 (5.7%)	Sunscreen
ZINC OXIDE (4.9%)	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. Rinse with water to remove. If swallowed, get medical help or contact a Poison Control Center right away.
- **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
- Apply stick following the curves of natural lip line. For added definition, use with a lip pencil

Other information

- Protect this 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, perfluorooctyl triethoxysilane, tocopheryl acetate, hydrogen dimethicone, phenoxyethanol, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, alumina, hexyl laurate, parfum (fragrance), caprylyl glycol, triethoxycaprylylsilane, chlorphenesin, crithmum maritimum extract, ceramide 3.

May contain:

CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77891 (titanium dioxide).

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

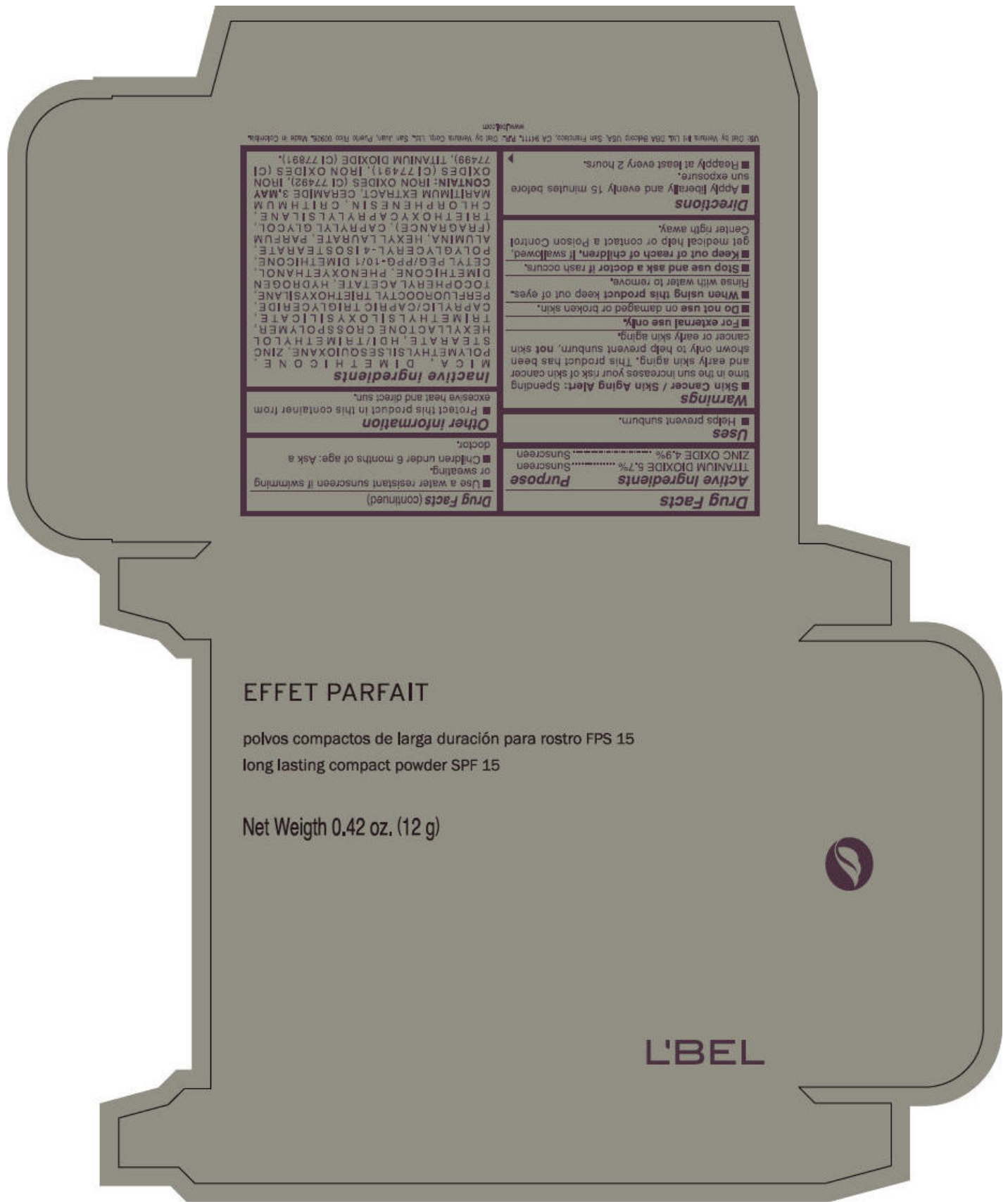
PRINCIPAL DISPLAY PANEL - 12 g Case Box - (CLAIRE 1) - Beige

EFFET PARFAIT

long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)

L'BEL



Drug Facts

Active Ingredients
 TITANIUM DIOXIDE 5.7%
 ZINC OXIDE 4.9%

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.
 ■ 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.

Drug Facts (continued)
 ■ Use a water resistant sunscreen if swimming or sweating.
 ■ Children under 6 months of age: Ask a doctor.
Other information
 ■ Protect this product in this container from excessive heat and direct sun.

Inactive ingredients
 MICA, DIMETHICONE, POLYMETHYLSILSESQUOXANE, ZINC STEARATE, HDI/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER, TRIMETHYLSILOXYLICATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, PERFLUOROOCTYL TRIFLUOROMETHANE, TOCOPHERYL ACETATE, HYDROGEN DIMETHICONE, PHENOXYETHANOL, CETYL PEG/PPG-10/1 DIMETHICONE, POLYGLYCERYL-4 ISOSTEARATE, ALUMINA, HEXYL LAURATE, PARFUM (FRAGRANCE), CAPRYLYL GLYCOL, TRIETHOXYCAPRYLYLSILANE, CHLORPHENESIN, CRITHMUM MARIIMUM EXTRACT, CERAMIDE 3, MAY CONTAIN: IRON OXIDES (CI 77492), IRON OXIDES (CI 77491), IRON OXIDES (CI 77499), TITANIUM DIOXIDE (CI 77891).

US: Own by Venus Kit Ltd, 20A Bldg USA, San Francisco, CA 94111, P.O. Box 10000, San Juan, Puerto Rico 00926, Made in Colombia
 www.lbel.com

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



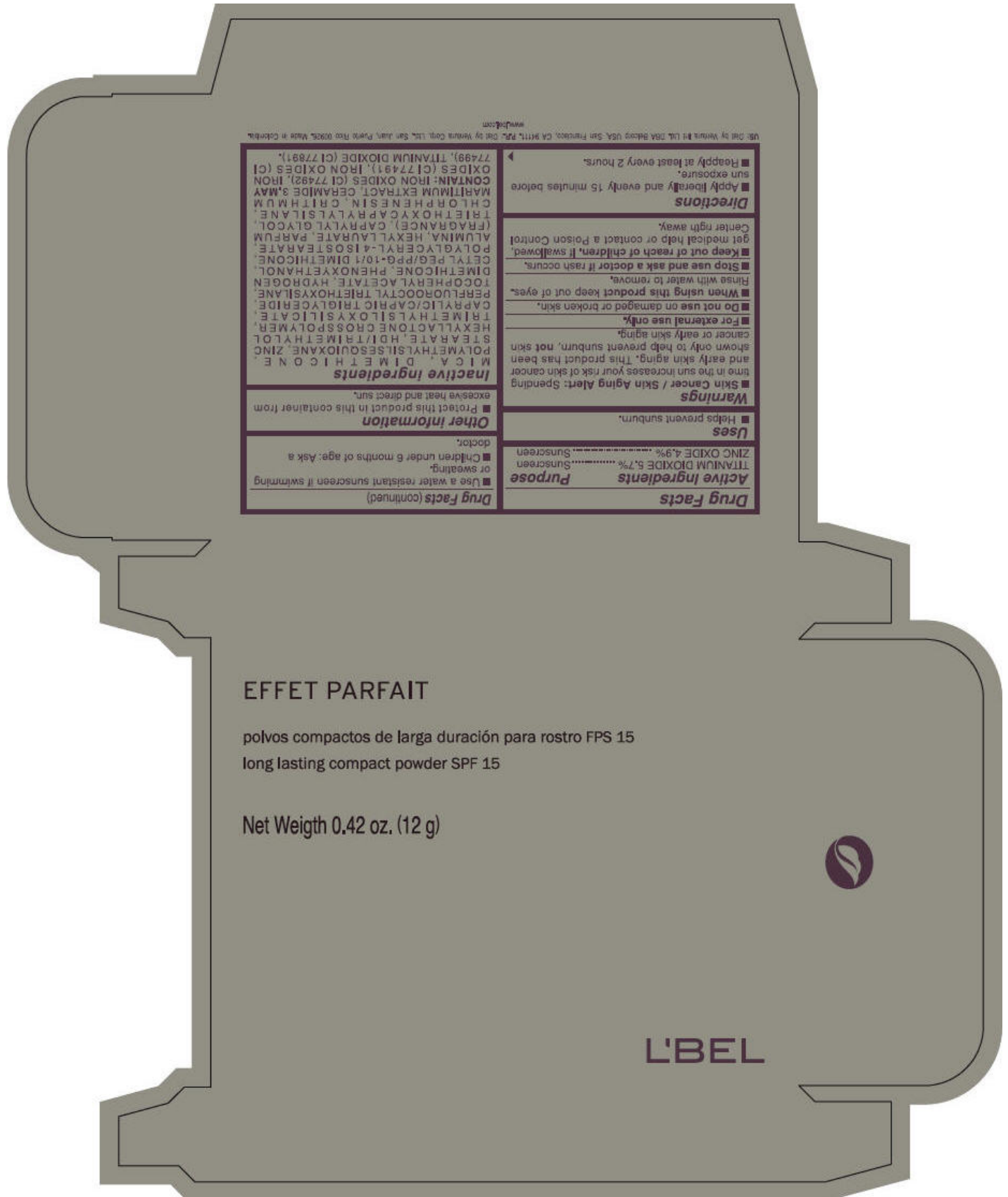
PRINCIPAL DISPLAY PANEL - 12 g Case Box - (CLAIRE 2) - Beige

EFFET PARFAIT

long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)

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Drug Facts
TITANIUM DIOXIDE 5.7% Sunscreen
ZINC OXIDE 4.9% Sunscreen

Purpose
Use a water resistant sunscreen if swimming or sweating.
Children under 6 months of age: Ask a doctor.

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

Inactive Ingredients
MICA, DIMETHICONE, POLYMETHYLSILSESQUOXANE, ZINC STEARATE, HDI/TRIMETHYLOL HEXYL LACTONE CROSSPOLYMER, TRIMETHYLSILOXYSLICATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, PERFLUOROOCTYL TRIFLUOROMETHANE, TOCOPHERYL ACETATE, HYDROGEN DIMETHICONE, PHENOXETHANOL, CETYL PEG/PPG-10/1 DIMETHICONE, POLYGLYCERYL-4 ISOSTEARATE, ALUMINA, HEXYL LAURATE, PARFUM (FRAGRANCE), CAPRYLYL GLYCOL, TRIETHOXYCAPRYLYLSILANE, CHLORPHENESIN, CRITHMUM MARTIUM EXTRACT, CERAMIDE 3, MAY CONTAIN: IRON OXIDES (CI 77492), IRON OXIDES (CI 77491), IRON OXIDES (CI 77499), TITANIUM DIOXIDE (CI 77891).

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.

EFFET PARFAIT

polvos compactos de larga duración para rostro FPS 15
long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)



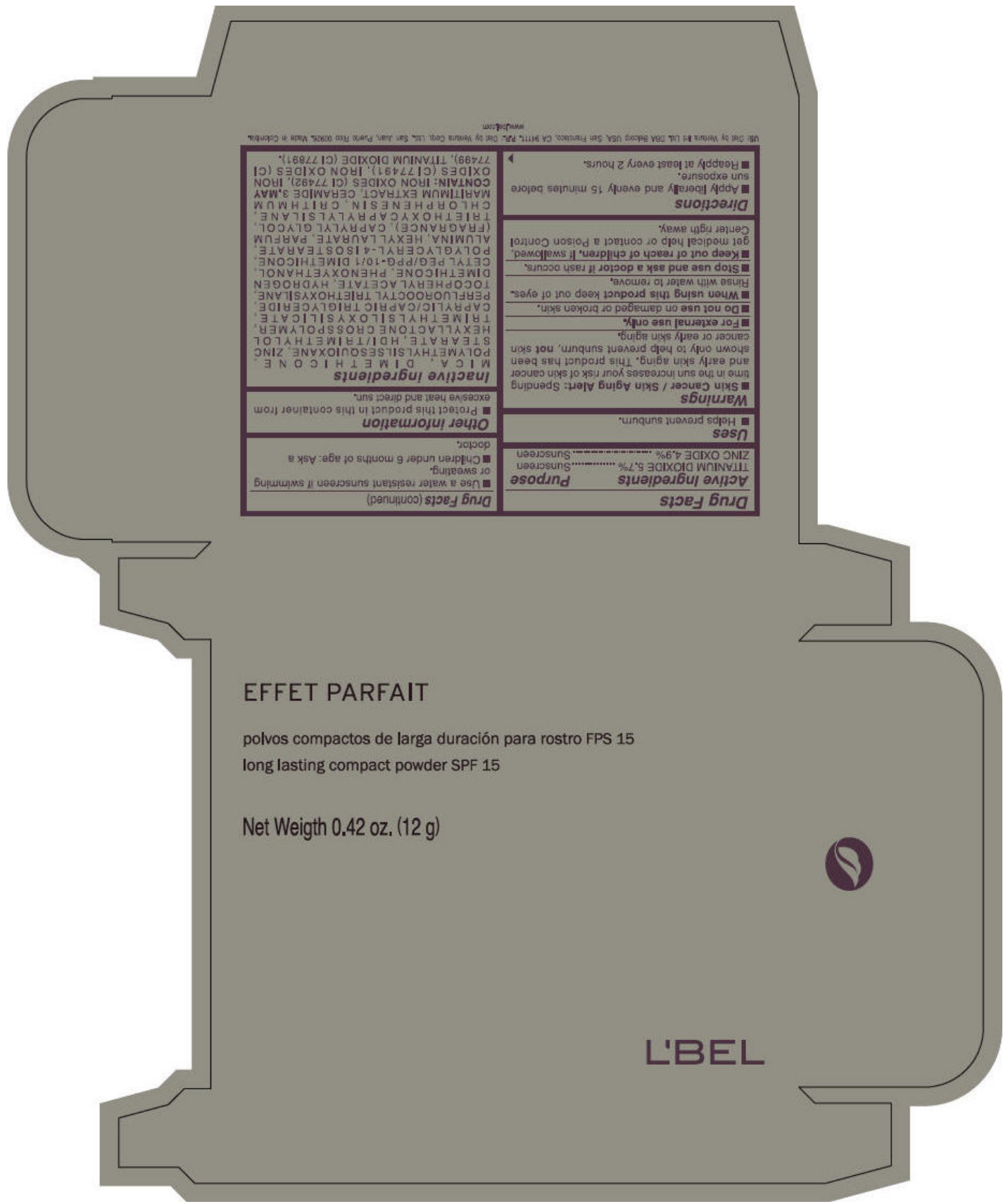
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EFFET PARFAIT

long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)

L'BEL



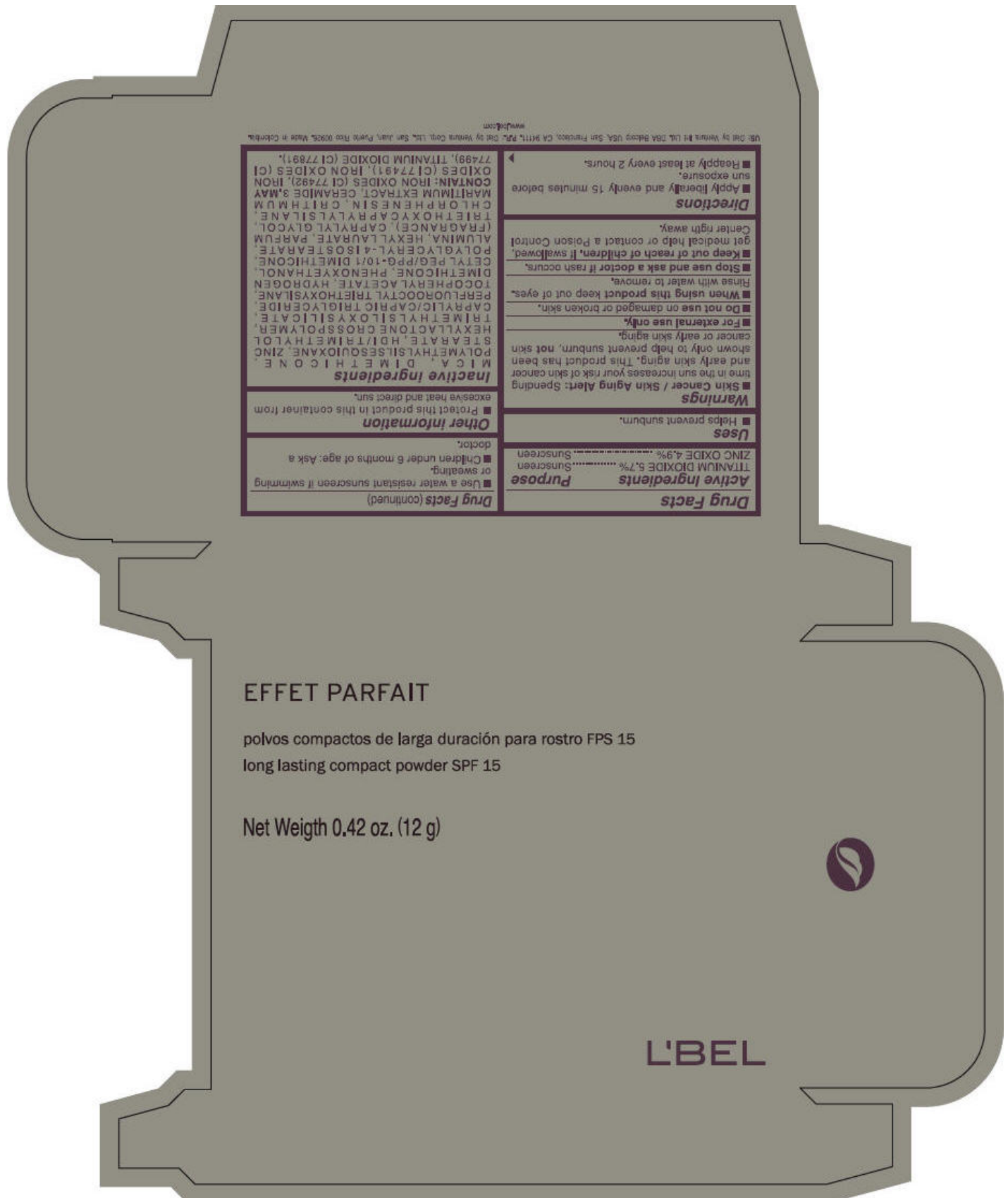
PRINCIPAL DISPLAY PANEL - 12 g Case Box - (CLAIRE 4) - Beige

EFFET PARFAIT

long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)

L'BEL



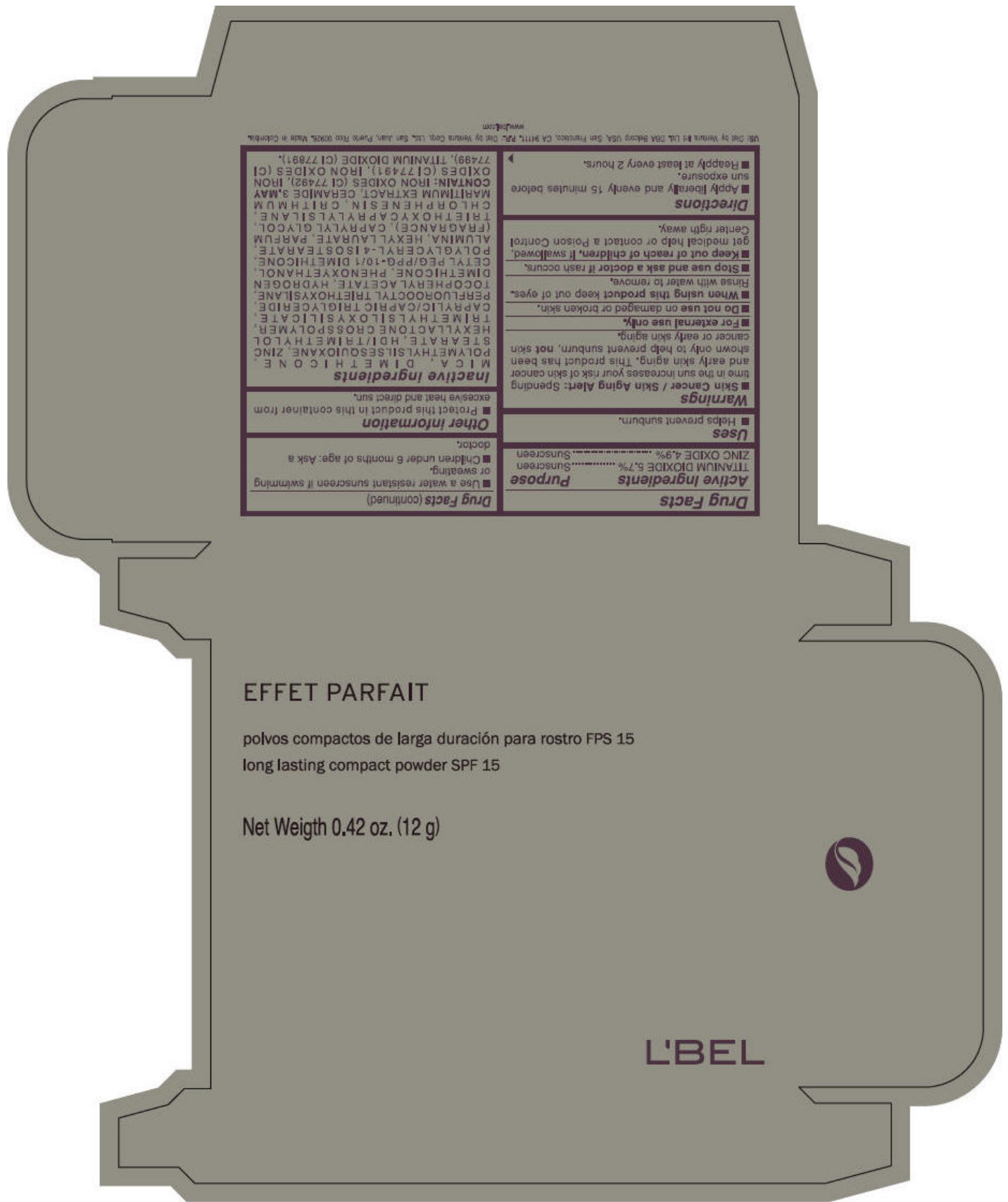
PRINCIPAL DISPLAY PANEL - 12 g Case Box - (MEDIUM 5) - Brown

EFFET PARFAIT

long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)

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Drug Facts

Active Ingredients
 TITANIUM DIOXIDE 5.7%
 ZINC OXIDE 4.9%

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.
 ■ 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.

Drug Facts (continued)
 ■ Use a water resistant sunscreen if swimming or sweating.
 ■ Children under 6 months of age: Ask a doctor.
Other information
 ■ Protect this product in this container from excessive heat and direct sun.

Inactive ingredients
 MICA, DIMETHICONE, POLYMETHYLSILSESQUOXANE, ZINC STEARATE, HDI/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER, TRIMETHYLSILOXYSELLACATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, PERFLUOROOCTYL TRIFLUOROMETHANE, TOCOPHERYL ACETATE, HYDROGEN DIMETHICONE, PHENOXYETHANOL, CETYL PEG/PPG-10/1 DIMETHICONE, POLYGLYCERYL-4 ISOSTEARATE, ALUMINA, HEXYL LAURATE, PARFUM (FRAGRANCE), CAPRYLYL GLYCOL, TRIETHOXYCAPRYLYLSILANE, CHLORPHENESIN, CRITHMUM MARIIMUM EXTRACT, CERAMIDE 3, MAY CONTAIN: IRON OXIDES (CI 77492), IRON OXIDES (CI 77491), IRON OXIDES (CI 77499), TITANIUM DIOXIDE (CI 77891).

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EFFET PARFAIT

polvos compactos de larga duración para rostro FPS 15
 long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)

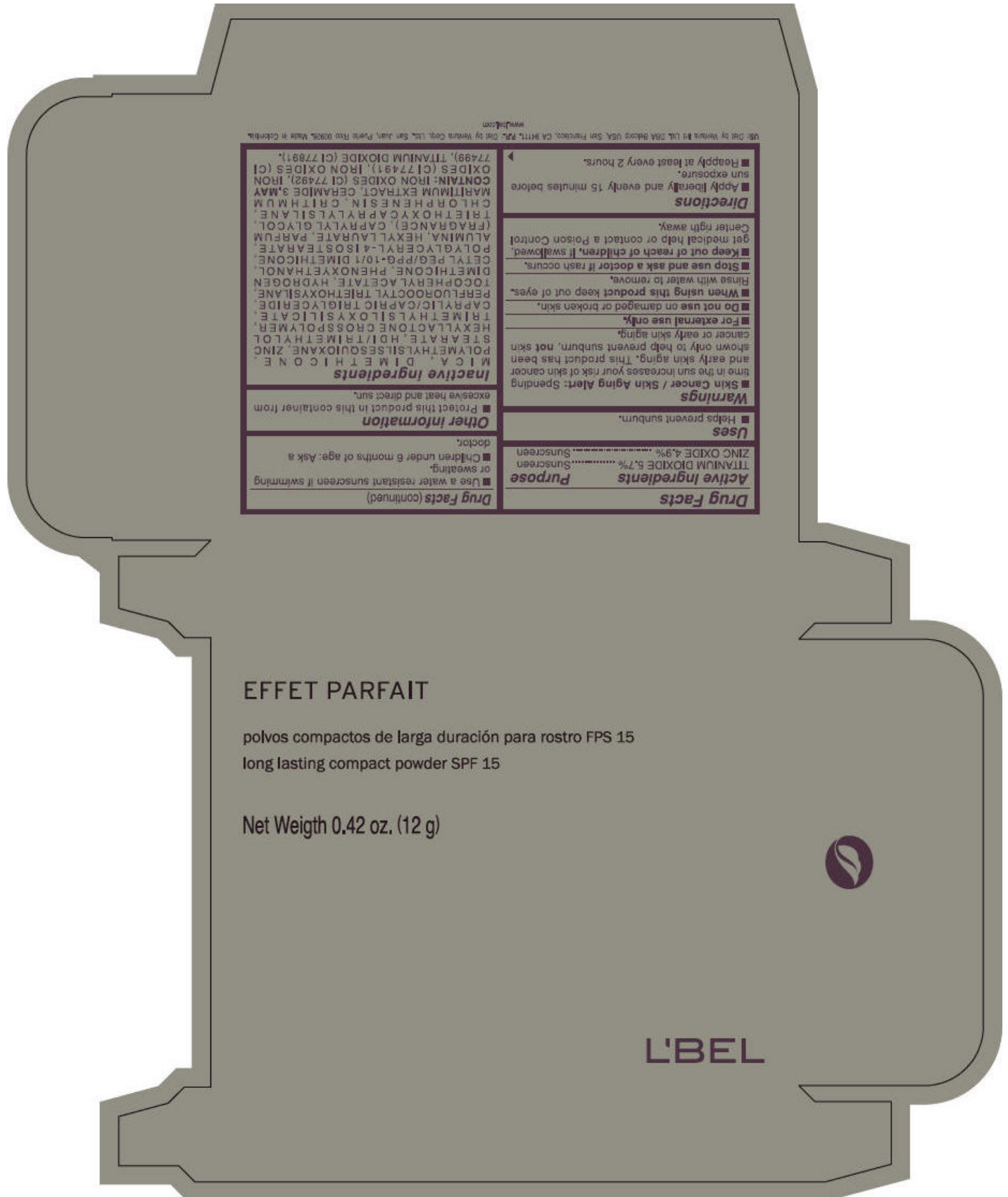
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PRINCIPAL DISPLAY PANEL - 12 g Case Box - (MEDIUM 6) - Brown
EFFET PARFAIT
 long lasting compact powder SPF 15

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)



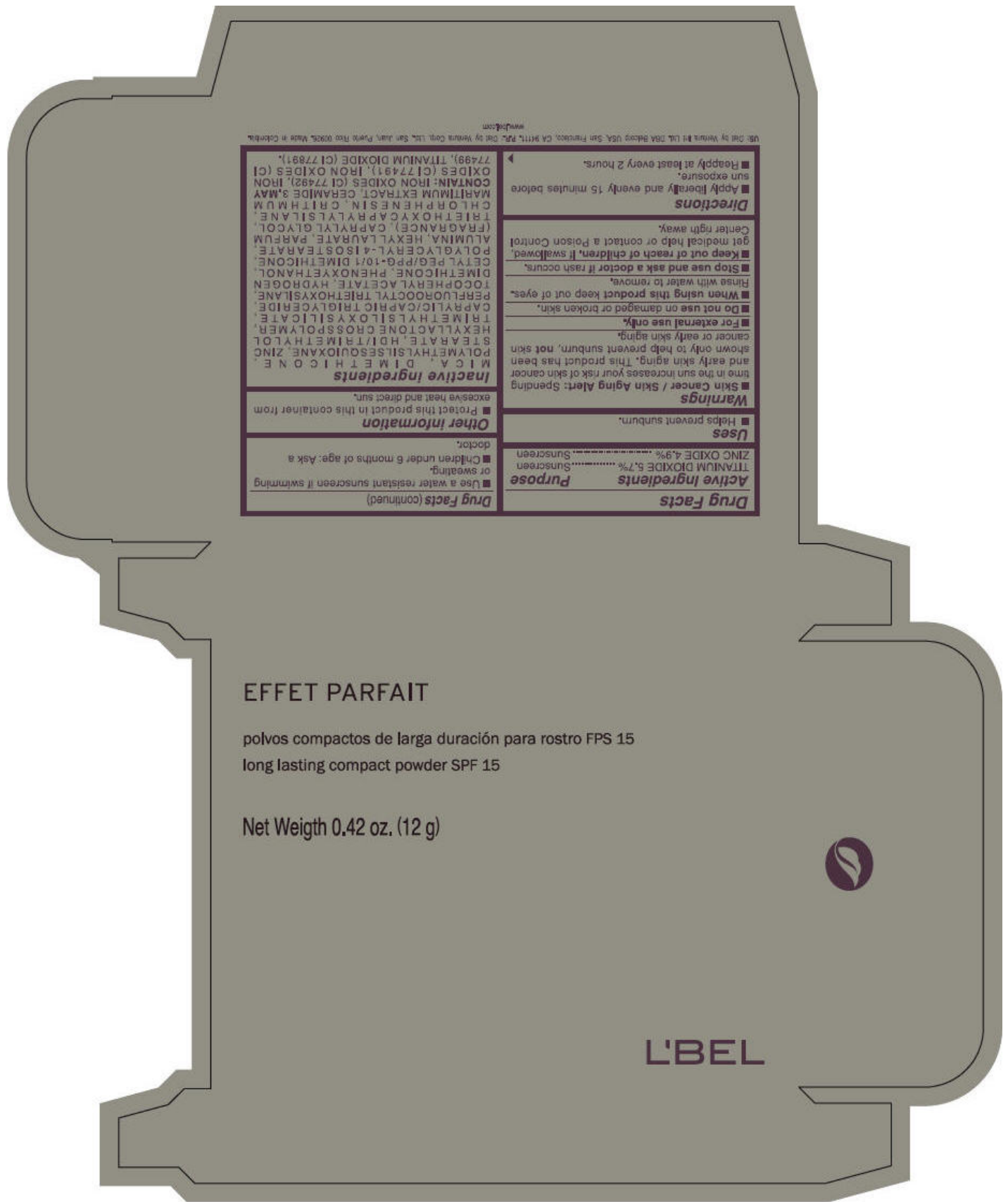
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EFFET PARFAIT

long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)

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EFFET PARFAIT

polvos compactos de larga duración para rostro FPS 15
 long lasting compact powder SPF 15

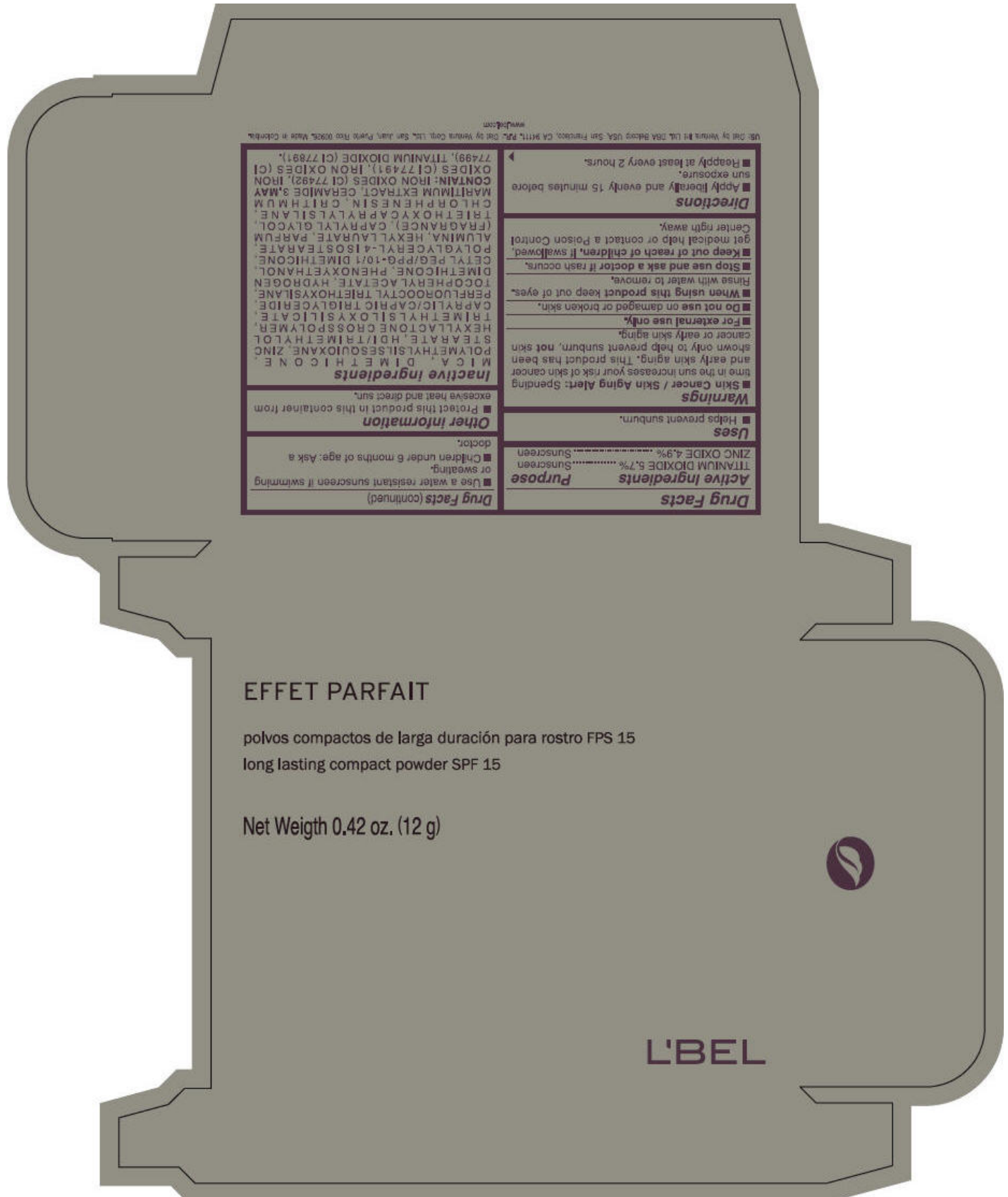
Net Weight 0.42 oz. (12 g)

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PRINCIPAL DISPLAY PANEL - 12 g Case Box - (OBSCURE 8) - Brown
EFFET PARFAIT
 long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)

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Drug Facts
Active Ingredients
TITANIUM DIOXIDE 5.7% Sunscreen
ZINC OXIDE 4.9% Sunscreen

Purpose
Use a water resistant sunscreen if swimming or sweating.
Children under 6 months of age: Ask a doctor.

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

Inactive Ingredients
MICA, DIMETHICONE, POLYMETHYLSILSESQUOXANE, ZINC STEARATE, HDI/TRIMETHYLOL HEXYL LACTONE CROSSPOLYMER, TRIMETHYLSILOXYSLICATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, PERFLUOROOCTYL TRIFLUOROMETHANE, TOCOPHERYL ACETATE, HYDROGEN DIMETHICONE, PHENOXETHANOL, CETYL PEG/PPG-10/1 DIMETHICONE, POLYGLYCERYL-4 ISOSTEARATE, ALUMINA, HEXYL LAURATE, PARFUM (FRAGRANCE), CAPRYLYL GLYCOL, TRIETHOXYCAPRYLYLSILANE, CHLORPHENESIN, CRITHMUM MARTIUM EXTRACT, CERAMIDE 3, MAY CONTAIN: IRON OXIDES (CI 77492), IRON OXIDES (CI 77491), IRON OXIDES (CI 77499), TITANIUM DIOXIDE (CI 77891).

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.
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.

EFFET PARFAIT

polvos compactos de larga duración para rostro FPS 15
long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)

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EFFET PARFAIT

long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)

L'BEL

Drug Facts

Active Ingredients
 TITANIUM DIOXIDE 5.7%
 ZINC OXIDE 4.9%

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.
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 ■ 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.

Drug Facts (continued)
 ■ Use a water resistant sunscreen if swimming or sweating.
 ■ Children under 6 months of age: Ask a doctor.
Other information
 ■ Protect this product in this container from excessive heat and direct sun.

Inactive ingredients
 MICA, DIMETHICONE, POLYMETHYLSILSESQUOXANE, ZINC STEARATE, HDI/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER, TRIMETHYLSILOXYSELLACATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, PERFLUOROOCTYL TRIFLUOROMETHANE, TOCOPHERYL ACETATE, HYDROGEN DIMETHICONE, PHENOXYETHANOL, CETYL PEG/PPG-10/1 DIMETHICONE, POLYGLYCERYL-4 ISOSTEARATE, ALUMINA, HEXYL LAURATE, PARFUM (FRAGRANCE), CAPRYLYL GLYCOL, TRIETHOXYCAPRYLYLSILANE, CHLORPHENESIN, CRITHMUM MARITIMUM EXTRACT, CERAMIDE 3, MAY CONTAIN: IRON OXIDES (CI 77492), IRON OXIDES (CI 77491), IRON OXIDES (CI 77499), TITANIUM DIOXIDE (CI 77891).

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EFFET PARFAIT

polvos compactos de larga duración para rostro FPS 15
 long lasting compact powder SPF 15

Net Weight 0.42 oz. (12 g)



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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUORO OCTYL TRIETHOXY SILANE (UNII: 814P46684U)	
.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)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
CERAMIDE 3 (UNII: 4370DF050B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-112-02	1 in 1 BOX		
1	NDC:13537-112-01	12 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2014	

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

zinc oxide and titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUORO OCTYL TRIETHOXY SILANE (UNII: 814P46684U)	
.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)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
CERAMIDE 3 (UNII: 4370DF050B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-113-06	1 in 1 BOX		
1	NDC:13537-113-05	12 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2014	

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

zinc oxide and titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-403
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUORO OCTYL TRIETHOXY SILANE (UNII: 814P46684U)	
.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)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
CERAMIDE 3 (UNII: 4370DF050B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-403-10	1 in 1 BOX		
1	NDC:13537-403-09	12 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2014	

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

zinc oxide and titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-114
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUORO OCTYL TRIETHOXYSILANE (UNII: 814P46684U)	
.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)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
CERAMIDE 3 (UNII: 4370DF050B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-114-14	1 in 1 BOX		
1	NDC:13537-114-13	12 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2014	

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

zinc oxide and titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-405
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUORO OCTYL TRIETHOXY SILANE (UNII: 814P46684U)	
.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)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
CERAMIDE 3 (UNII: 4370DF050B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-405-18	1 in 1 BOX		
1	NDC:13537-405-17	12 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO FPS 15 /LONG LASTING COMPACT SPF 15 (MEDIUM 6) - BROWN

zinc oxide and titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-406
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUORO OCTYL TRIETHO XYSILANE (UNII: 814P46684U)	
.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)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
CERAMIDE 3 (UNII: 4370DF050B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-406-22	1 in 1 BOX		
1	NDC:13537-406-21	12 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2014	

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

zinc oxide and titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-407
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUORO OCTYL TRIETHOXY SILANE (UNII: 814P46684U)	
.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)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
CERAMIDE 3 (UNII: 4370DF050B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-407-26	1 in 1 BOX		
1	NDC:13537-407-25	12 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2014	

LBEL EFFET PARFAIT POLVOS COMPACTOS DE LARGA DURACION PARA ROSTRO FPS 15 /LONG LASTING COMPACT SPF 15 (OBSCURE 8) - BROWN

zinc oxide and titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-408
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUORO OCTYL TRIETHOXY SILANE (UNII: 814P46684U)	
.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)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
CERAMIDE 3 (UNII: 4370DF050B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-408-30	1 in 1 BOX		
1	NDC:13537-408-29	12 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2014	

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

zinc oxide and titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-409
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC STEARATE (UNII: H92E6QA4FV)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUORO OCTYL TRIETHOXY SILANE (UNII: 814P46684U)	
.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)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
CERAMIDE 3 (UNII: 4370DF050B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-409-34	1 in 1 BOX		
1	NDC:13537-409-33	12 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/27/2014	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-112, 13537-113, 13537-403, 13537-114, 13537-405, 13537-406, 13537-407, 13537-408, 13537-409)

Revised: 1/2014

Ventura Corporation LTD