

**LBEL DIVINE POLVOS COMPACTOS DOBLE USO FPS 15 EDICION DE LUJO DORADO/DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION CLAIRE 1-2-3- titanium dioxide, zinc oxide, and octinoxate powder**

**LBEL DIVINE POLVOS COMPACTOS DOBLE USO FPS 15 EDICION DE LUJO DORADO/DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION CLAIRE 4- titanium dioxide, zinc oxide, and octinoxate powder**

**LBEL DIVINE POLVOS COMPACTOS DOBLE USO FPS 15 EDICION DE LUJO DORADO/DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION MEDIUM 5- titanium dioxide, zinc oxide, and octinoxate powder**

**LBEL DIVINE POLVOS COMPACTOS DOBLE USO FPS 15 EDICION DE LUJO DORADO/DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION MEDIUM 6- titanium dioxide, zinc oxide, and octinoxate powder**

**LBEL DIVINE POLVOS COMPACTOS DOBLE USO FPS 15 EDICION DE LUJO DORADO/DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION MEDIUM 7- titanium dioxide, zinc oxide, and octinoxate powder**

**LBEL DIVINE POLVOS COMPACTOS DOBLE USO FPS 15 EDICION DE LUJO DORADO/DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION OBSCURE 8-9- titanium dioxide, zinc oxide, and octinoxate 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.*

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**L'BEL**

**DIVINE Polvos compactos doble uso FPS 15 edición de lujo dorado/Double use compact SPF 15 gold deluxe edition**

***Drug Facts***

### **Active Ingredients**

TITANIUM DIOXIDE (6.2393%), ZINC OXIDE (4.9%), OCTINOXATE (3.0%)

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

**Other information**

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

**Inactive ingredients**

MICA, POLYMETHYLSILSESQUIOXANE, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, DIMETHICONE, MAGNESIUM STEARATE, TRIMETHYLSILOXYSILICATE, ISOSTEARYL NEOPENTANOATE, HYDROGEN DIMETHICONE, TOCOPHERYL ACETATE, PHENOXYETHANOL, ALUMINA, TRIETHOXYCAPRYLYLSILANE, PARFUM (FRAGRANCE), CAPRYLYL GLYCOL, CERAMIDE 3, CHLORPHENESIN. MAY CONTAIN: CI 77492 (IRON OXIDES), CI 77491 (IRON OXIDES), CI 77891 (TITANIUM DIOXIDE ), CI 77499 (IRON OXIDES).

US: Dist by Ventura Int Ltd. DBA Belcorp USA, San Francisco, CA 94111.

**PRINCIPAL DISPLAY PANEL - 10 g Cartridge Box - Claire 1-2-3****DIVINE**

Polvos compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

10 g e (.35 oz.)

**L'BEL**



## DIVINE

Polvos compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

10 g e (.35 oz.)

# L'BEL

### **Drug Facts**

#### **Active Ingredients**

Titanium Dioxide 6.2393% , Zinc Oxide 4.9 %,  
Octinoxate 3.0%

#### **Purpose**

Sunscreen

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

**Other information:**

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

**Inactive ingredients:**

mica, polymethylsilsesquioxane, hdi/trimethylol hexyllactone crosspolymer, dimethicone, magnesium stearate, trimethylsiloxysilicate, isostearyl neopentanoate, hydrogen dimethicone, tocopheryl acetate, phenoxyethanol, alumina, triethoxycaprylylsilane, parfum (fragrance), caprylyl glycol, ceramide 3, chlorphenesin. **May contain:** CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77891 (titanium dioxide), CI 77499 (iron oxides)

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

CLAIRE 1-2-3

**PRINCIPAL DISPLAY PANEL - 10 g Cartridge Box - Claire 4**

**DIVINE**

Polvos compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

10 g e (.35 oz.)

**L'BEL**



## DIVINE

Polvos compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

10 g e (.35 oz.)

# L'BEL

### **Drug Facts**

#### **Active Ingredients**

Titanium Dioxide 6.2393% , Zinc Oxide 4.9 %,

Octinoxate 3.0%.....Sunscreen

#### **Purpose**

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

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

**Inactive ingredients:**  
mica, polymethylsilsesquioxane, hdi/trimethylol hexyllactone crosspolymer, dimethicone, magnesium stearate, trimethylsiloxysilicate, isostearyl neopentanoate, hydrogen dimethicone, tocopheryl acetate, phenoxyethanol, alumina, triethoxycaprylylsilane, parfum (fragrance), caprylyl glycol, ceramide 3, chlorphenesin. **May contain:** CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77891 (titanium dioxide), CI 77499 (iron oxides)

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CLAIRE 4

**PRINCIPAL DISPLAY PANEL - 10 g Cartridge Box - Medium 5**

**DIVINE**

Polvos compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

10 g e (.35 oz.)

**L'BEL**



## DIVINE

Polvos compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

10 g e (.35 oz.)

# L'BEL

### **Drug Facts**

#### **Active Ingredients**

Titanium Dioxide 6.2393% , Zinc Oxide 4.9 % ,  
Octinoxate 3.0%

#### **Purpose**

Sunscreen

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

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

**Inactive ingredients:**  
mica, polymethylsilsesquioxane, hdi/trimethylol hexyllactone crosspolymer, dimethicone, magnesium stearate, trimethylsiloxysilicate, isostearyl neopentanoate, hydrogen dimethicone, tocopheryl acetate, phenoxyethanol, alumina, triethoxycaprylylsilane, parfum (fragrance), caprylyl glycol, ceramide 3, chlorphenesin **May contain:** CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77891 (titanium dioxide), CI 77499 (iron oxides)

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**MEDIUM 5**

**PRINCIPAL DISPLAY PANEL - 10 g Cartridge Box - Medium 6**

**DIVINE**

Polvos compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

10 g e (.35 oz.)

**L'BEL**





## DIVINE

Polvos compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

10 g e (.35 oz.)

# L'BEL

### **Drug Facts**

#### **Active Ingredients**

Titanium Dioxide 6.2393% , Zinc Oxide 4.9 %,

Octinoxate 3.0%.....Sunscreen

#### **Purpose**

**Uses:** ■ Help prevents 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

prevent sunburn, not skin cancer or early skin aging. ■ For external use only. ■ Do not use on damage 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. ■ Children under 6 months of age: Ask a doctor. ■ Reapply at least every 2 hours. ■ Use a water resistant sunscreen if swimming or sweating.

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

**Inactive ingredients:**  
mica, polymethylsilsesquioxane, hdi/trimethylol hexyllactone crosspolymer, dimethicone, magnesium stearate, trimethylsiloxysilicate, isostearyl neopentanoate, hydrogen dimethicone, tocopheryl acetate, phenoxyethanol, alumina, triethoxycaprylylsilane, parfum (fragrance), caprylyl glycol, ceramide 3, chlorphenesin. **May contain:** CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77891 (titanium dioxide), CI 77499 (iron oxides)

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MEDIUM 6

## PRINCIPAL DISPLAY PANEL - 10 g Cartridge Box - Medium 7

### DIVINE

Polvos compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

10 g e (.35 oz.)

L'BEL



## DIVINE

Polvos compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

10 g e (.35 oz.)

# L'BEL

### **Drug Facts**

#### **Active Ingredients**

Titanium Dioxide 6.2393% , Zinc Oxide 4.9 % ,  
Octinoxate 3.0%

#### **Purpose**

Sunscreen

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

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

**Inactive ingredients:**  
mica, polymethylsilsesquioxane, hdi/trimethylol hexyllactone crosspolymer, dimethicone, magnesium stearate, trimethylsiloxysilicate, isostearyl neopentanoate, hydrogen dimethicone, tocopheryl acetate, phenoxyethanol, alumina, triethoxycaprylylsilane, parfum (fragrance), caprylyl glycol, ceramide 3, chlorphenesin. May contain: CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77891 (titanium dioxide), CI 77499 (iron oxides).

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MEDIUM 7

## PRINCIPAL DISPLAY PANEL - 10 g Cartridge Box - Obscure 8-9

### DIVINE

Polvos compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

10 g e (.35 oz.)

L'BEL



## DIVINE

Polvos compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

10 g e (.35 oz.)

# L'BEL

### **Drug Facts**

#### **Active Ingredients**

Titanium Dioxide 6.2393% , Zinc Oxide 4.9 %,

Octinoxate 3.0%.....Sunscreen

#### **Purpose**

**Uses:** ■ Help prevents 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

prevent sunburn, hot skin cancer or early skin aging. ■ For external use only. ■ Do not use on damage 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. ■ Children under 6 months of age: Ask a doctor. ■ Reapply at least every 2 hours. ■ Use a water resistant sunscreen if swimming or sweating.

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

**Inactive ingredients:**  
mica, polymethylsilsesquioxane, hdi/trimethylol hexyllactone crosspolymer, dimethicone, magnesium stearate, trimethylsiloxysilicate, isostearyl neopentanoate, hydrogen dimethicone, tocopheryl acetate, phenoxyethanol, alumina, triethoxycaprylylsilane, parfum (fragrance), caprylyl glycol, ceramide 3, chlorphenesin. **May contain:** CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77891 (titanium dioxide), CI 77499 (iron oxides)

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OBSCURE 8-9

**LBEL DIVINE POLVOS COMPACTOS DOBLE USO FPS 15 EDICION DE LUJO DORADO/DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION CLAIRE 1-2-3**

titanium dioxide, zinc oxide, and octinoxate powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-056
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.062393 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

ISO STEARYL NEOPENTANOATE (UNII: 411THY156Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

### Product Characteristics

Color	RED (Rose)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-056-02	1 in 1 BOX		
1	NDC:14783-056-01	10 g in 1 CARTRIDGE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/27/2013	

## LBEL DIVINE POLVOS COMPACTOS DOBLE USO FPS 15 EDICION DE LUJO DORADO/DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION CLAIRE 4

titanium dioxide, zinc oxide, and octinoxate powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-057
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.062393 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ISO STEARYL NEOPENTANOATE (UNII: 411THY156Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

**Product Characteristics**

Color	RED (Rose lightly yellowish)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-057-02	1 in 1 BOX		
1	NDC:14783-057-01	10 g in 1 CARTRIDGE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/27/2013	

**LBEL DIVINE POLVOS COMPACTOS DOBLE USO FPS 15 EDICION DE LUJO DORADO/DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION MEDIUM 5**

titanium dioxide, zinc oxide, and octinoxate powder

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-058
Route of Administration	TOPICAL		



**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.062393 g in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>MICA</b> (UNII: V8A1AW0880)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>ISOSTEARYL NEOPENTANOATE</b> (UNII: 411THY156Q)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CERAMIDE 3</b> (UNII: 4370DF050B)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	

**Product Characteristics**

<b>Color</b>	BROWN (Beige)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-058-02	1 in 1 BOX		
1	NDC:14783-058-01	10 g in 1 CARTRIDGE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/27/2013	

**LBEL DIVINE POLVOS COMPACTOS DOBLE USO FPS 15 EDICION DE LUJO DORADO/DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION MEDIUM 6**

titanium dioxide, zinc oxide, and octinoxate powder

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14783-059
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.062393 g in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>MICA</b> (UNII: V8A1AW0880)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>ISOSTEARYL NEOPENTANOATE</b> (UNII: 411THY156Q)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CERAMIDE 3</b> (UNII: 4370DF050B)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	

## Product Characteristics

<b>Color</b>	BROWN (Yellowish Beige)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:14783-059-02	1 in 1 BOX		
1	NDC:14783-059-01	10 g in 1 CARTRIDGE		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352	05/27/2013	

**LBEL DIVINE POLVOS COMPACTOS DOBLE USO FPS 15 EDICION DE LUJO DORADO/DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION MEDIUM 7**

titanium dioxide, zinc oxide, and octinoxate powder

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14783-060
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.062393 g in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>MICA</b> (UNII: V8A1AW0880)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>ISO STEARYL NEOPENTANOATE</b> (UNII: 411THY156Q)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CERAMIDE 3</b> (UNII: 4370DF050B)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	

**Product Characteristics**

<b>Color</b>	BROWN (Light Reddish Beige)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:14783-060-02	1 in 1 BOX		
1	NDC:14783-060-01	10 g in 1 CARTRIDGE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/27/2013	

## LBEL DIVINE POLVOS COMPACTOS DOBLE USO FPS 15 EDICION DE LUJO DORADO/DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION OBSCURE 8-9

titanium dioxide, zinc oxide, and octinoxate powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-061
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.062393 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

### Product Characteristics

Color	BROWN (Reddish Beige)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-061-02	1 in 1 BOX		
1	NDC:14783-061-01	10 g in 1 CARTRIDGE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/27/2013	

**Labeler** - Ventura International LTD. (603192787)**Establishment**

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-056, 14783-057, 14783-058, 14783-059, 14783-060, 14783-061)

Revised: 5/2013

Ventura International LTD.