

LBEL FILLING EFFECT FOUNDATION SPF 10 (CLAIRE 1) - BEIGE- octinoxate liquid
LBEL FILLING EFFECT FOUNDATION SPF 10 (CLAIRE 2) - BEIGE- octinoxate liquid
LBEL FILLING EFFECT FOUNDATION SPF 10 (CLAIRE 3) - BEIGE- octinoxate liquid
LBEL FILLING EFFECT FOUNDATION SPF 10 (CLAIRE 4) - BEIGE- octinoxate liquid
LBEL FILLING EFFECT FOUNDATION SPF 10 (MEDIUM 5) - BROWN- octinoxate liquid
LBEL FILLING EFFECT FOUNDATION SPF 10 (MEDIUM 6) - BROWN- octinoxate liquid
LBEL FILLING EFFECT FOUNDATION SPF 10 (MEDIUM 7) - BROWN- octinoxate liquid
LBEL FILLING EFFECT FOUNDATION SPF 10 (OBSCURE 8) - BROWN- octinoxate liquid
LBEL FILLING EFFECT FOUNDATION SPF 10 (OBSCURE 9) - BROWN- octinoxate liquid
Ventura Corporation LTD

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

L'BEL FILLING EFFECT FOUNDATION SPF 10

Drug Facts

Active Ingredients

Octinoxate 7 %

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.
- 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

AQUA (WATER), CYCLOMETHICONE, CYCLOPENTASILOXANE, CYCLOHEXASILOXANE, SODIUM CHLORIDE, PEG/PPG-18/18 DIMETHICONE, DIMETHICONE, NYLON-12 FLUORESCENT BRIGHTENER 230 SALT, DIMETHICONOL, DIAZOLIDINYL UREA, CETEARYL DIMETHICONE CROSSPOLYMER, METHYLPARABEN, PARFUM (FRAGRANCE), PROPYLPARABEN, POLYVINYLALCOHOL CROSSPOLYMER, SODIUM HYALURONATE.

MAY CONTAIN

TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77492), IRON OXIDES (CI 77499), IRON OXIDES (CI 77491), DIMETHICONE

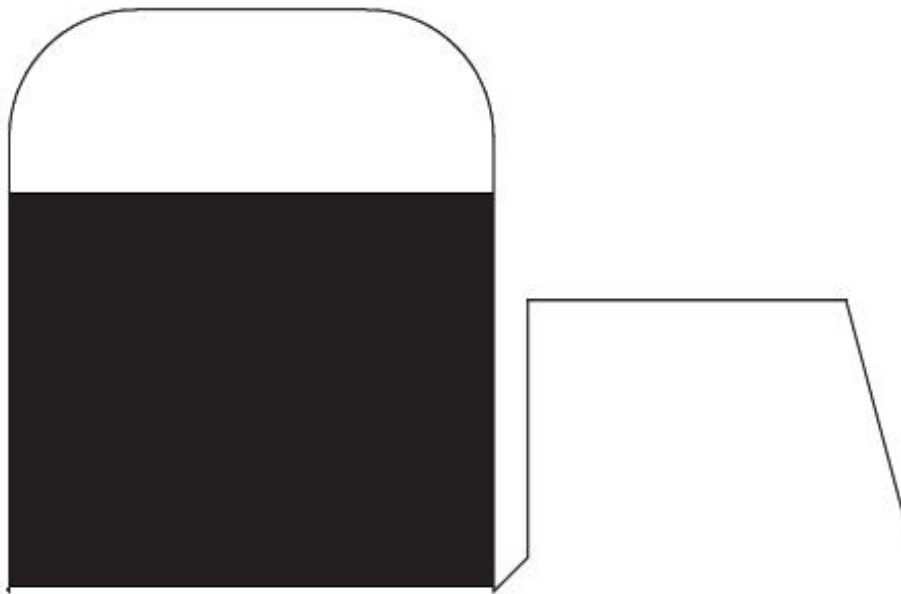
Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926.

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box - (Claire 1) - Beige**L'BEL**

EFFET
PARFAIT

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)



L'BEL

**EFFET
PARFAIT**

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)

Drug Facts

Active Ingredients

Octinoxate 7.0 %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.

Drug Facts (continued)

- **When using this product** keep out of eyes. Rinse with water to remove.

- **Stop use and ask a doctor** if rash occurs

- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

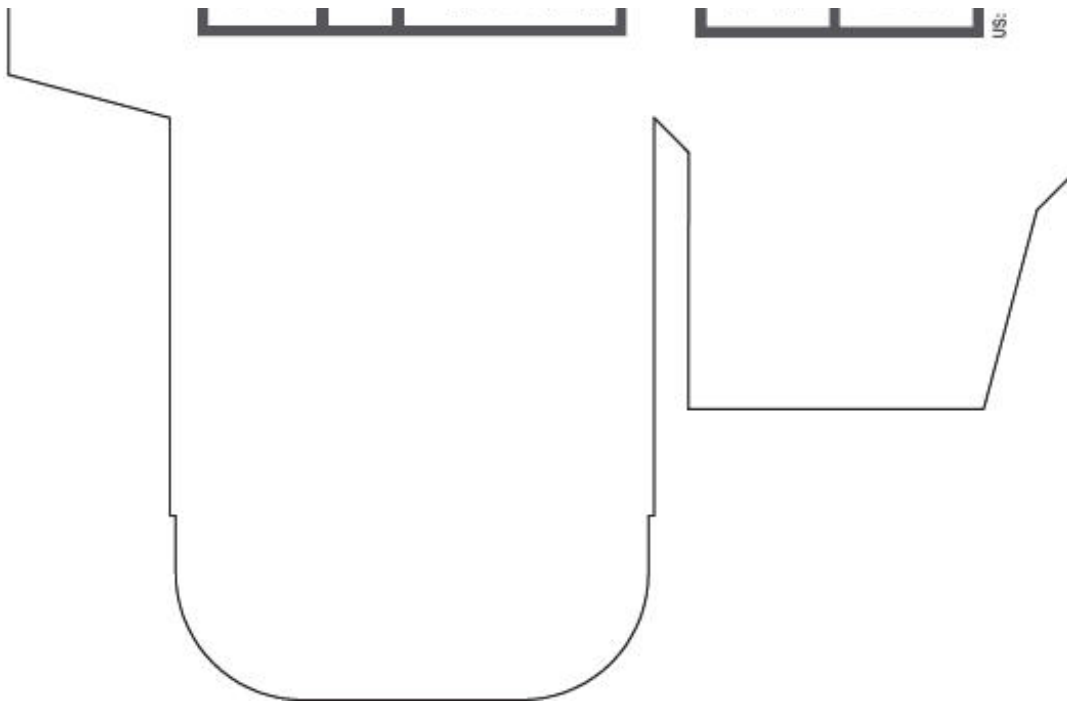
Drug Facts (continued)

Other information

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

Inactive ingredients Aqua (water), cyclomethicone, cyclopentasiloxane, cyclohexasiloxane, sodium chloride, peg/ppg-18/18 dimethicone, dimethicone, nylon-12 fluorescent brightener 230 salt, dimethiconol, diazolidinyl urea, cetearyl dimethicone crosspolymer, methylparaben, parium (fragrance), propylparaben, polyvinylalcohol crosspolymer, sodium hyaluronate. **May contain:** titanium dioxide (CI 77891), iron oxides (CI 77492), iron oxides (CI 77499), iron oxides (CI 77491), methicone.

Distributed by Ventura International Ltd. DBA Belcorp USA, San Francisco, CA 94111. P.R.: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Columbia. www.bel.com



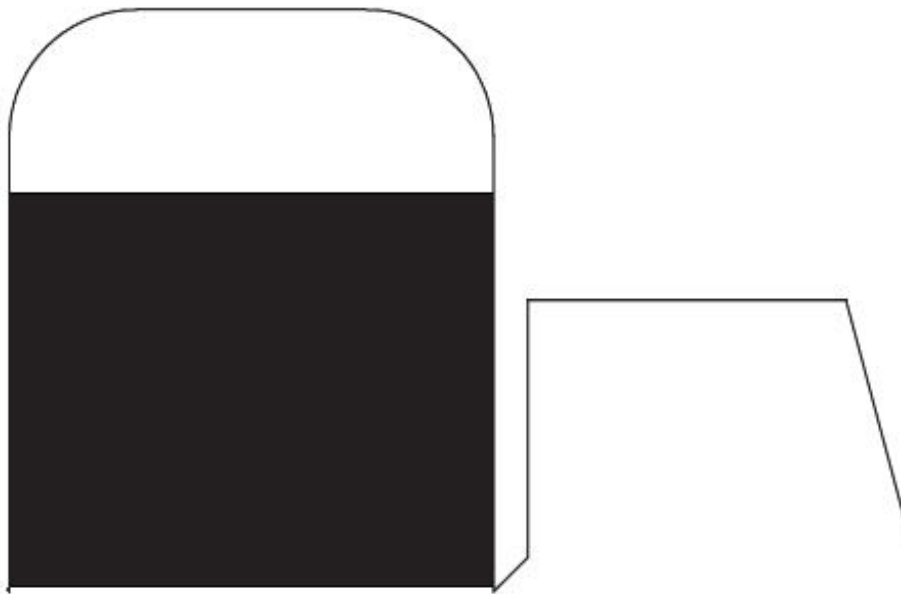
PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box - (Claire 2) - Beige

L'BEL

EFFET
PARFAIT

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)



L'BEL

**EFFET
PARFAIT**

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)

Drug Facts

Active Ingredients

Octinoxate 7.0 %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.

Drug Facts (continued)

- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor** if rash occurs
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

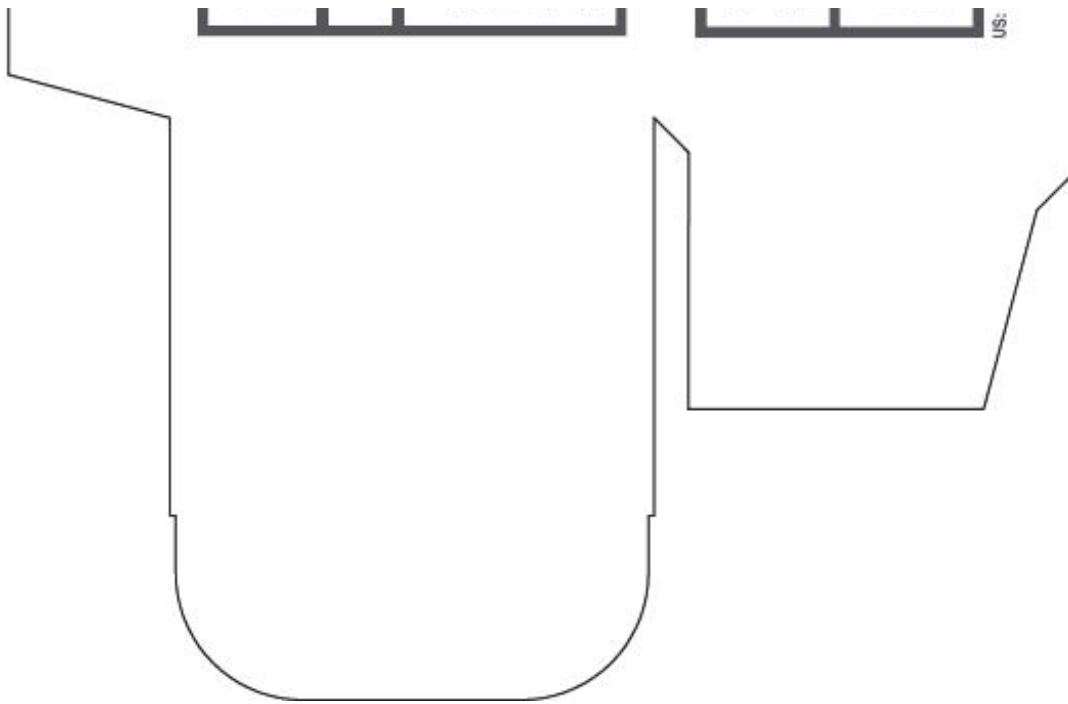
Drug Facts (continued)

Other information

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

Inactive ingredients Aqua (water), cyclomethicone, cyclopentasiloxane, cyclohexasiloxane, sodium chloride, peg/ppg-18/18 dimethicone, dimethicone, nylon-12 fluorescent brightener 230 salt, dimethiconol, diazolidinyl urea, cetearyl dimethicone crosspolymer, methylparaben, parium (fragrance), propylparaben, polyvinylalcohol crosspolymer, sodium hyaluronate. **May contain:** titanium dioxide (CI 77891), iron oxides (CI 77492), iron oxides (CI 77499), iron oxides (CI 77491), methicone.

Distributed by Ventura International Ltd. DBA Belcorp USA, San Francisco, CA 94111. P.R.: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Columbia. www.bel.com



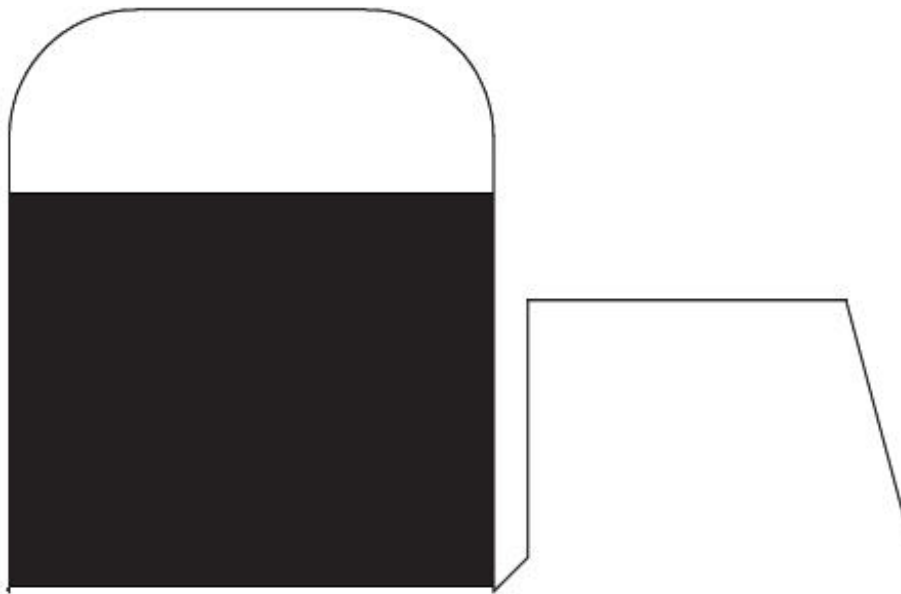
PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box - (Claire 3) - Beige

L'BEL

EFFET
PARFAIT

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)



L'BEL

**EFFET
PARFAIT**

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)

Drug Facts

Active Ingredients

Octinoxate 7.0 %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.

Drug Facts (continued)

- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor** if rash occurs
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

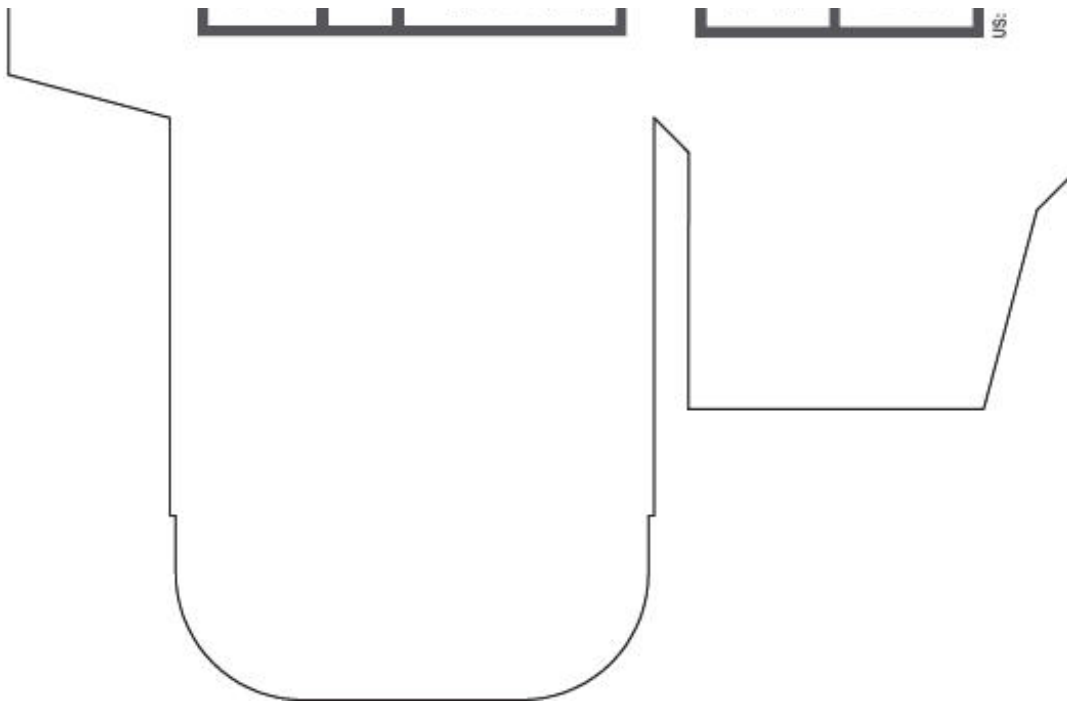
Drug Facts (continued)

Other information

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

Inactive ingredients Aqua (water), cyclomethicone, cyclopentasiloxane, cyclohexasiloxane, sodium chloride, peg/ppg-18/18 dimethicone, dimethicone, nylon-12 fluorescent brightener 230 salt, dimethiconol, diazolidinyl urea, cetearyl dimethicone crosspolymer, methylparaben, parium (fragrance), propylparaben, polyvinylalcohol crosspolymer, sodium hyaluronate. **May contain:** titanium dioxide (CI 77891), iron oxides (CI 77492), iron oxides (CI 77499), iron oxides (CI 77491), methicone.

Distributed by Ventura International Ltd. DBA Belcorp USA, San Francisco, CA 94111, P.R.: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Columbia. www.bel.com

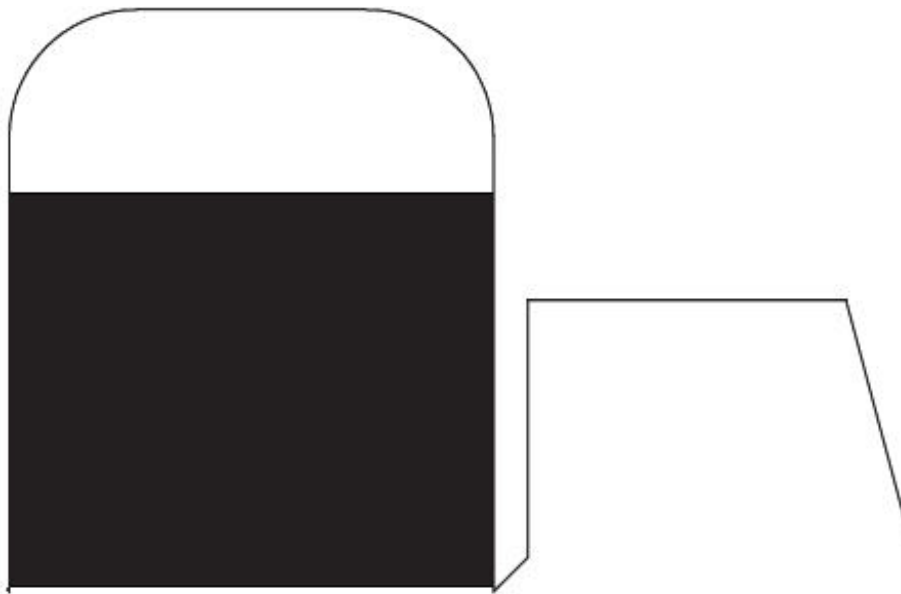


PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box - (Claire 4) - Beige

L'BEL

EFFET
PARFAIT

filling effect
foundation SPF 10
30 ml e (1 fl.oz.)



L'BEL

**EFFET
PARFAIT**

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)

Drug Facts

Active Ingredients

Octinoxate 7.0 %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.

Drug Facts (continued)

- **When using this product** keep out of eyes. Rinse with water to remove.

- **Stop use and ask a doctor** if rash occurs

- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

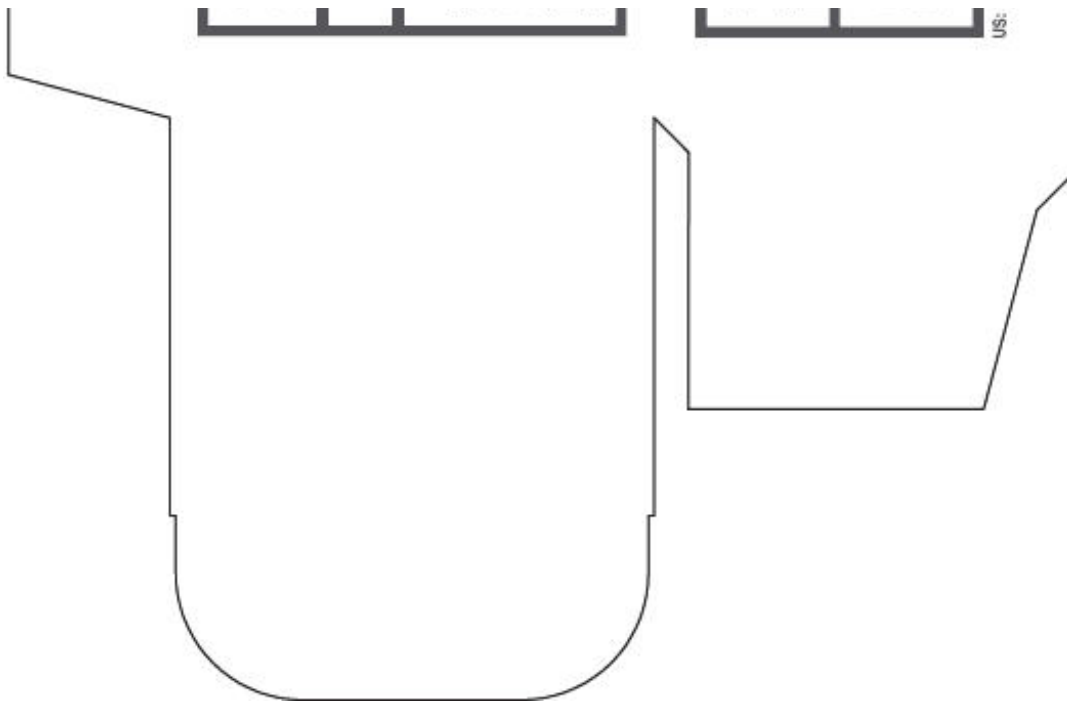
Drug Facts (continued)

Other information

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

Inactive ingredients Aqua (water), cyclomethicone, cyclopentasiloxane, cyclohexasiloxane, sodium chloride, peg/ppg-18/18 dimethicone, dimethicone, nylon-12 fluorescent brightener 230 salt, dimethiconol, diazolidinyl urea, cetearyl dimethicone crosspolymer, methylparaben, parium (fragrance), propylparaben, polyvinylalcohol crosspolymer, sodium hyaluronate. **May contain:** titanium dioxide (CI 77891), iron oxides (CI 77492), iron oxides (CI 77499), iron oxides (CI 77491), methicone.

Distributed by Ventura International Ltd., DBA Belcorp USA, San Francisco, CA 94111, P.R.: Distributed by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Columbia. www.bel.com

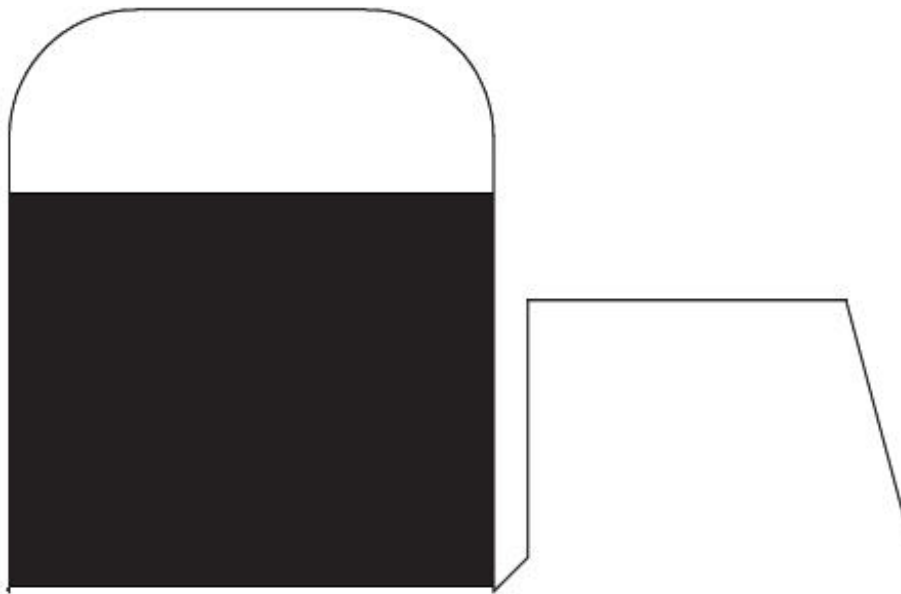


PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box - (Medium 5) - Brown

L'BEL

EFFET
PARFAIT

filling effect
foundation SPF 10
30 ml e (1 fl.oz.)



L'BEL

**EFFET
PARFAIT**

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)

Drug Facts

Active Ingredients

Octinoxate 7.0 %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.

Drug Facts (continued)

- **When using this product** keep out of eyes. Rinse with water to remove.

- **Stop use and ask a doctor** if rash occurs

- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

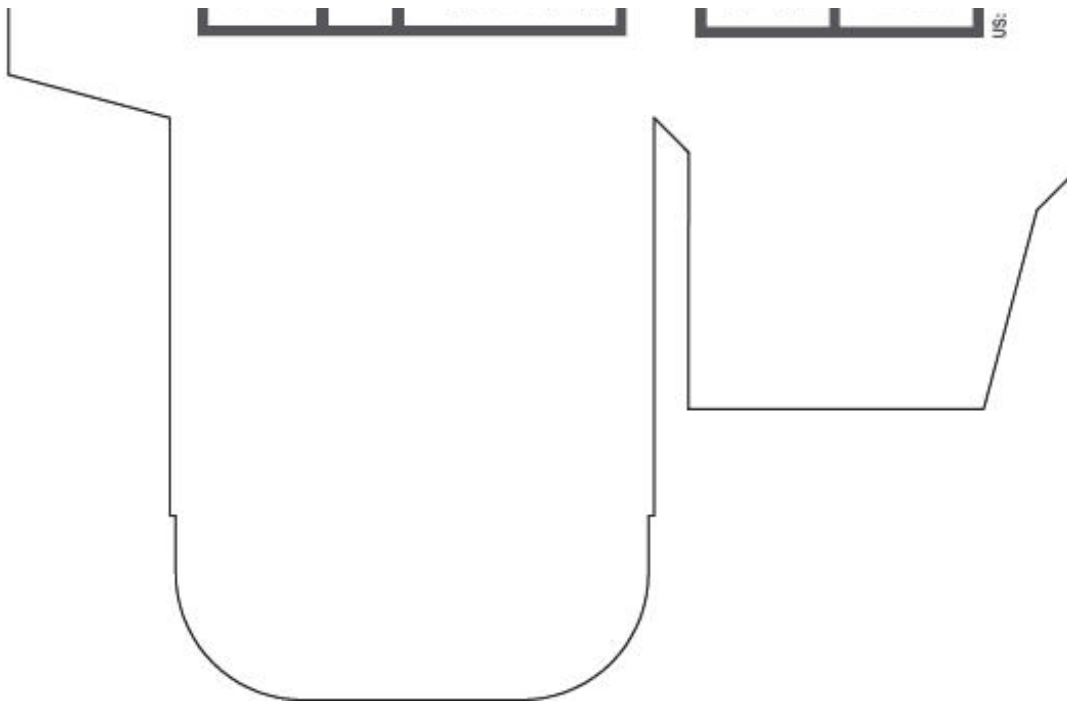
Drug Facts (continued)

Other information

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

Inactive ingredients Aqua (water), cyclomethicone, cyclopentasiloxane, cyclohexasiloxane, sodium chloride, peg/ppg-18/18 dimethicone, dimethicone, nylon-12 fluorescent brightener 230 salt, dimethiconol, diazolidinyl urea, cetearyl dimethicone crosspolymer, methylparaben, parium (fragrance), propylparaben, polyvinylalcohol crosspolymer, sodium hyaluronate. **May contain:** titanium dioxide (CI 77891), iron oxides (CI 77492), iron oxides (CI 77499), iron oxides (CI 77491), methicone.

Distributed by Ventura International Ltd., DBA Belcorp USA, San Francisco, CA 94111, P.R.: Distributed by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Columbia. www.bel.com



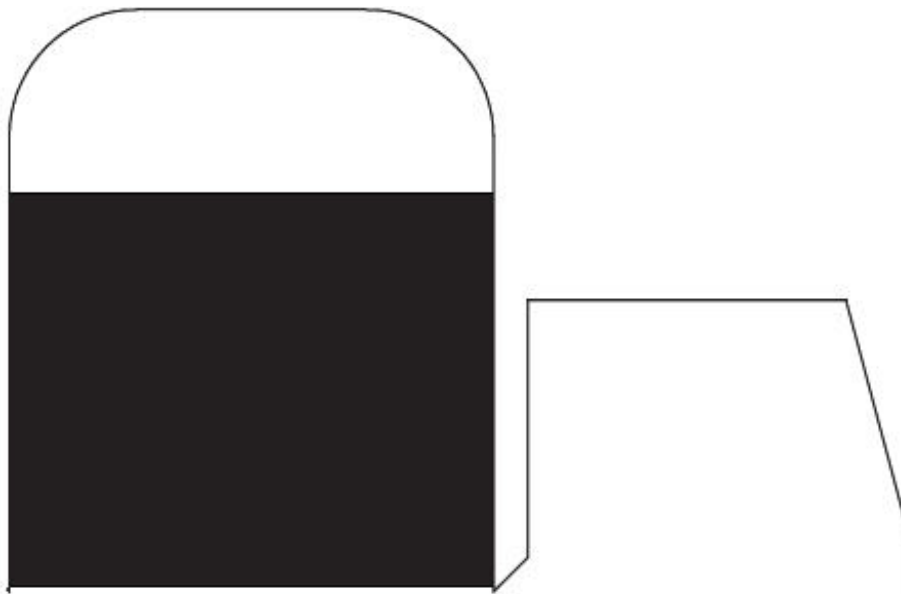
PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box - (Medium 6) - Brown

L'BEL

EFFET
PARFAIT

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)



L'BEL

**EFFET
PARFAIT**

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)

Drug Facts

Active Ingredients

Octinoxate 7.0 %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.

Drug Facts (continued)

- **When using this product** keep out of eyes. Rinse with water to remove.

- **Stop use and ask a doctor** if rash occurs

- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

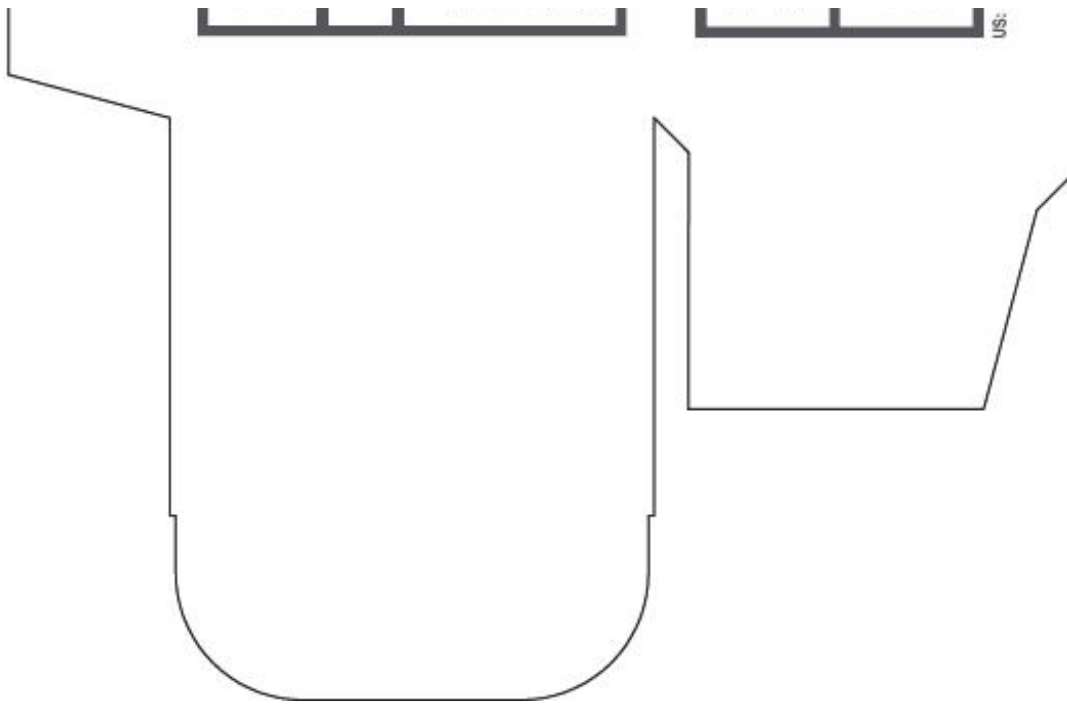
Drug Facts (continued)

Other information

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

Inactive ingredients Aqua (water), cyclomethicone, cyclopentasiloxane, cyclohexasiloxane, sodium chloride, peg/ppg-18/18 dimethicone, dimethicone, nylon-12 fluorescent brightener 230 salt, dimethiconol, diazolidinyl urea, cetearyl dimethicone crosspolymer, methylparaben, parium (fragrance), propylparaben, polyvinylalcohol crosspolymer, sodium hyaluronate. **May contain:** titanium dioxide (CI 77891), iron oxides (CI 77492), iron oxides (CI 77499), iron oxides (CI 77491), methicone.

Distributed by Ventura International Ltd. DBA Belcorp USA, San Francisco, CA 94111. P.R.: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Columbia. www.bel.com

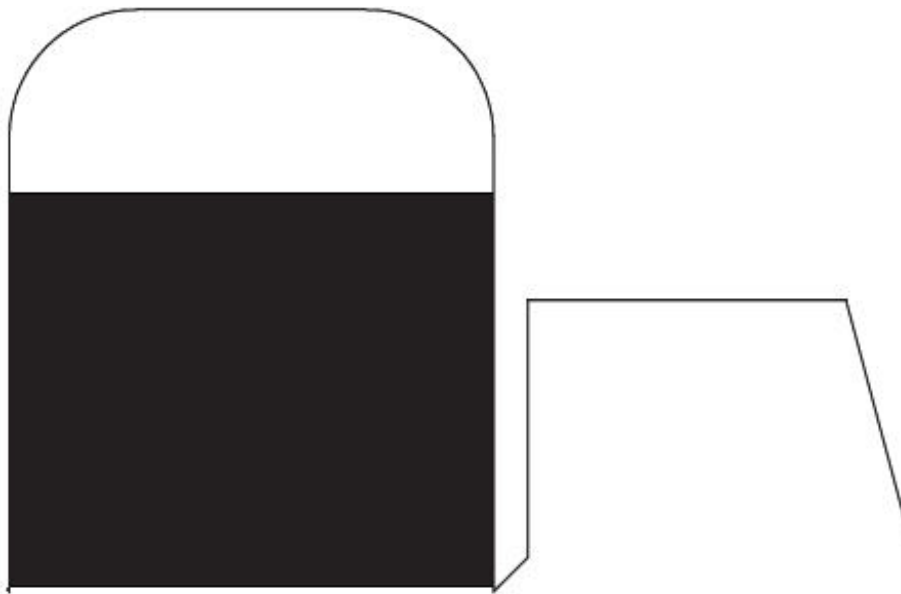


PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box - (Medium 7) - Brown

L'BEL

EFFET
PARFAIT

filling effect
foundation SPF 10
30 ml e (1 fl.oz.)



L'BEL

**EFFET
PARFAIT**

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)

Drug Facts

Active Ingredients

Octinoxate 7.0 %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.

Drug Facts (continued)

- **When using this product** keep out of eyes. Rinse with water to remove.

- **Stop use and ask a doctor** if rash occurs

- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

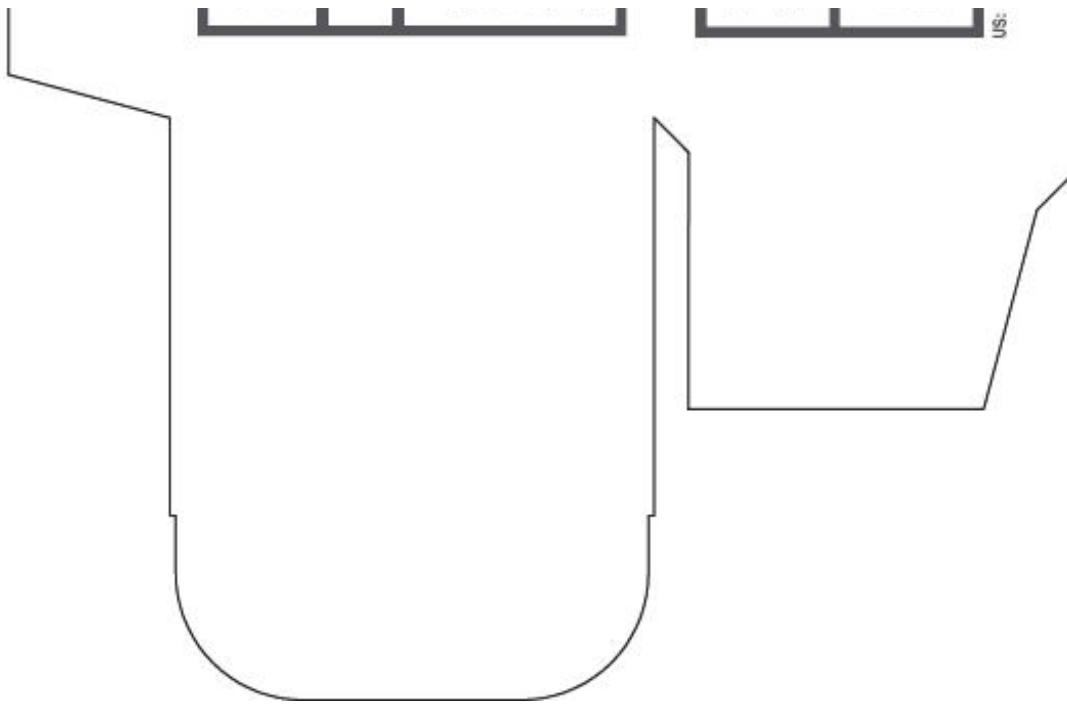
Drug Facts (continued)

Other information

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

Inactive ingredients Aqua (water), cyclomethicone, cyclopentasiloxane, cyclohexasiloxane, sodium chloride, peg/ppg-18/18 dimethicone, dimethicone, nylon-12 fluorescent brightener 230 salt, dimethiconol, diazolidinyl urea, cetearyl dimethicone crosspolymer, methylparaben, parium (fragrance), propylparaben, polyvinylalcohol crosspolymer, sodium hyaluronate. **May contain:** titanium dioxide (CI 77891), iron oxides (CI 77492), iron oxides (CI 77499), iron oxides (CI 77491), methicone.

Distributed by Ventura International Ltd., DBA Belcorp USA, San Francisco, CA 94111, P.R.: Distributed by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Columbia. www.bel.com



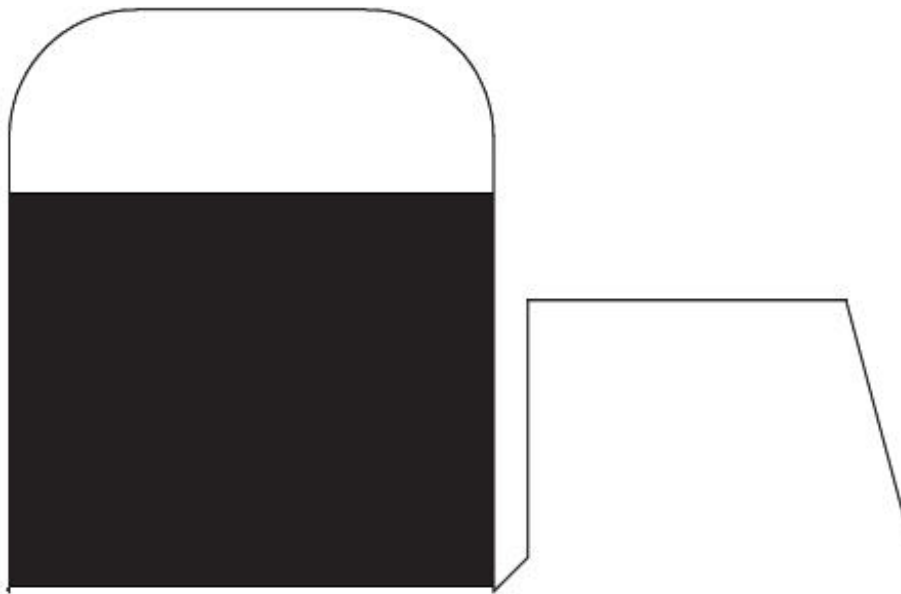
PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box - (Obscure 8) - Brown

L'BEL

EFFET
PARFAIT

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)



L'BEL

**EFFET
PARFAIT**

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)

Drug Facts

Active Ingredients

Octinoxate 7.0 %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.

Drug Facts (continued)

- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor** if rash occurs
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

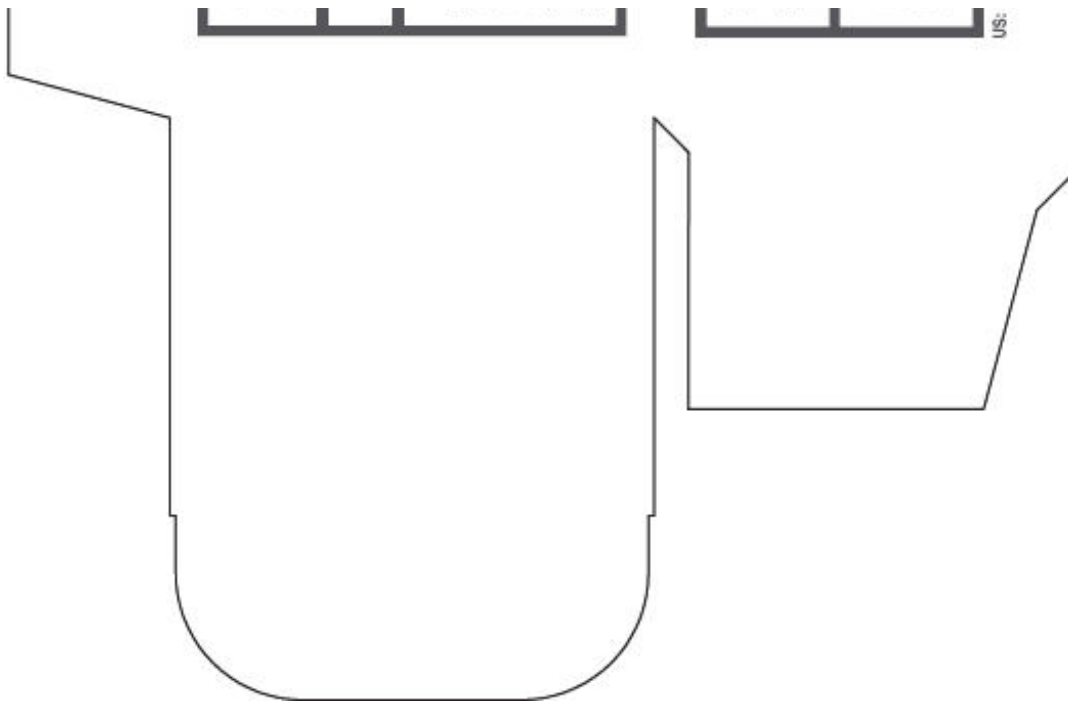
Drug Facts (continued)

Other information

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

Inactive ingredients Aqua (water), cyclomethicone, cyclopentasiloxane, cyclohexasiloxane, sodium chloride, peg/ppg-18/18 dimethicone, dimethicone, nylon-12 fluorescent brightener 230 salt, dimethiconol, diazolidinyl urea, cetearyl dimethicone crosspolymer, methylparaben, parium (fragrance), propylparaben, polyvinylalcohol crosspolymer, sodium hyaluronate. **May contain:** titanium dioxide (CI 77891), iron oxides (CI 77492), iron oxides (CI 77499), iron oxides (CI 77491), methicone.

Distributed by Ventura International Ltd. DBA Belcorp USA, San Francisco, CA 94111, P.R.: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Columbia. www.bel.com



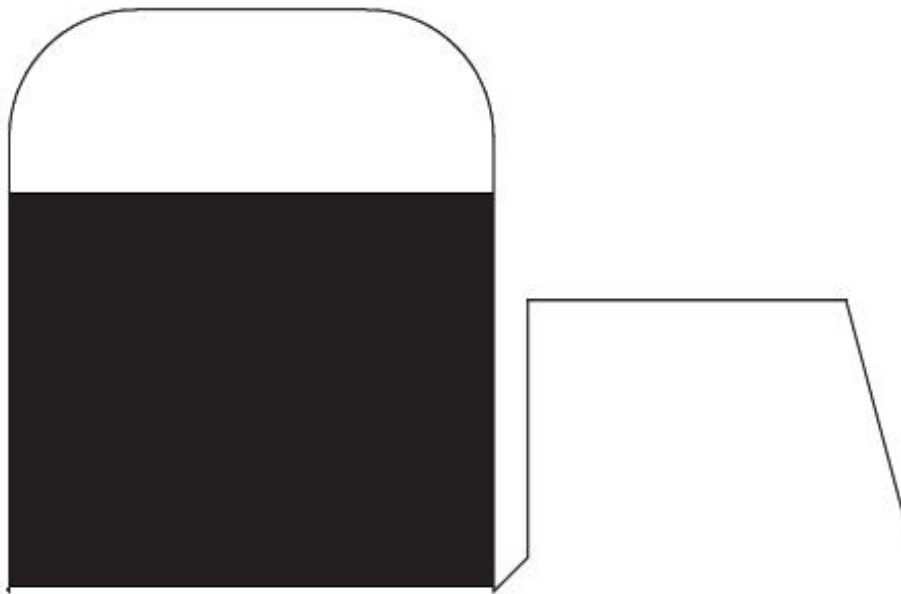
PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box - (Obscure 9) - Brown

L'BEL

EFFET
PARFAIT

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)



L'BEL

**EFFET
PARFAIT**

filling effect
foundation SPF 10

30 ml e (1 fl.oz.)

Drug Facts

Active Ingredients

Octinoxate 7.0 %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.

Drug Facts (continued)

- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor** if rash occurs
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

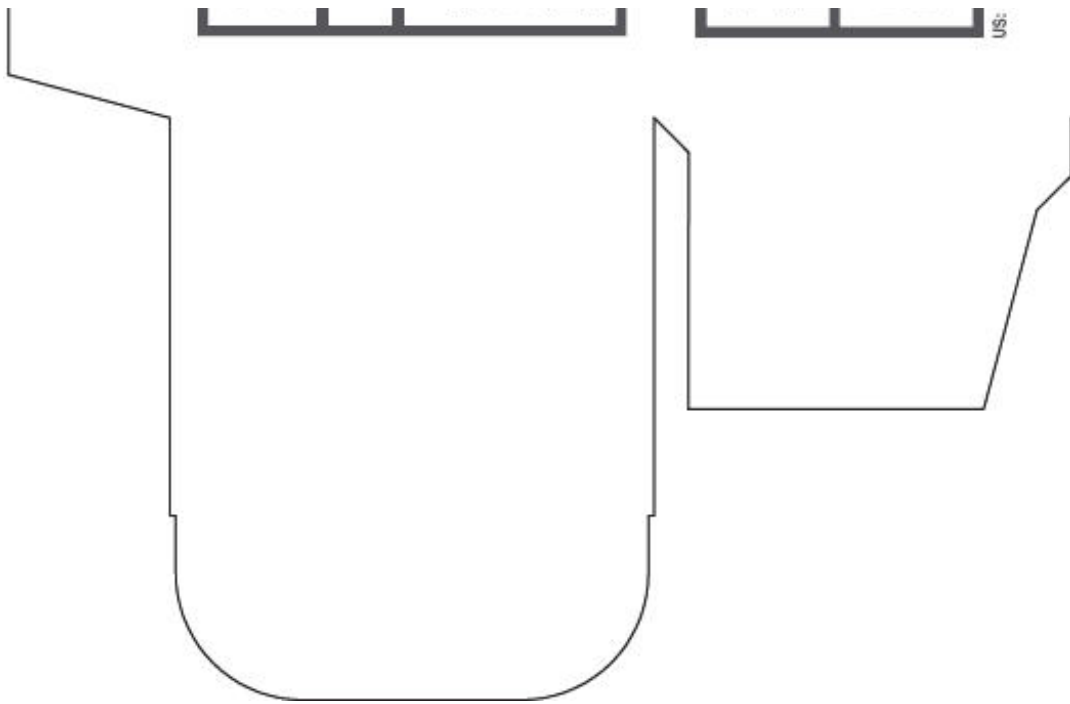
Drug Facts (continued)

Other information

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

Inactive ingredients Aqua (water), cyclomethicone, cyclopentasiloxane, cyclohexasiloxane, sodium chloride, peg/ppg-18/18 dimethicone, dimethicone, nylon-12 fluorescent brightener 230 salt, dimethiconol, diazolidinyl urea, cetearyl dimethicone crosspolymer, methylparaben, parium (fragrance), propylparaben, polyvinylalcohol crosspolymer, sodium hyaluronate. **May contain:** titanium dioxide (CI 77891), iron oxides (CI 77492), iron oxides (CI 77499), iron oxides (CI 77491), methicone.

Distributed by Ventura International Ltd., DBA Belcorp USA, San Francisco, CA 94111, P.R.: Distributed by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Columbia. www.bel.com



LBEL FILLING EFFECT FOUNDATION SPF 10 (CLAIRE 1) - BEIGE

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-200-02	1 in 1 BOX		
1	NDC:13537-200-01	30 mL in 1 BOTTLE		
2	NDC:13537-200-04	1 in 1 BOX		
2	NDC:13537-200-03	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL FILLING EFFECT FOUNDATION SPF 10 (CLAIRE 2) - BEIGE

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-201-06	1 in 1 BOX		
1	NDC:13537-201-05	30 mL in 1 BOTTLE		
2	NDC:13537-201-08	1 in 1 BOX		
2	NDC:13537-201-07	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL FILLING EFFECT FOUNDATION SPF 10 (CLAIRE 3) - BEIGE

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-202-10	1 in 1 BOX		
1	NDC:13537-202-09	30 mL in 1 BOTTLE		
2	NDC:13537-202-12	1 in 1 BOX		
2	NDC:13537-202-11	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL FILLING EFFECT FOUNDATION SPF 10 (CLAIRE 4) - BEIGE

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-203-14	1 in 1 BOX		
1	NDC:13537-203-13	30 mL in 1 BOTTLE		
2	NDC:13537-203-16	1 in 1 BOX		
2	NDC:13537-203-15	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL FILLING EFFECT FOUNDATION SPF 10 (MEDIUM 5) - BROWN

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-204
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THI5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC10H)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-204-18	1 in 1 BOX		

1	NDC:13537-204-17	30 mL in 1 BOTTLE		
2	NDC:13537-204-20	1 in 1 BOX		
2	NDC:13537-204-19	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL FILLING EFFECT FOUNDATION SPF 10 (MEDIUM 6) - BROWN

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-205
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC10H)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-205-22	1 in 1 BOX		
1	NDC:13537-205-21	30 mL in 1 BOTTLE		
2	NDC:13537-205-24	1 in 1 BOX		

2	NDC:13537-205-23	3 mL in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part352	12/16/2013		

LBEL FILLING EFFECT FOUNDATION SPF 10 (MEDIUM 7) - BROWN

octinoxate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-206
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-206-26	1 in 1 BOX		
1	NDC:13537-206-25	30 mL in 1 BOTTLE		
2	NDC:13537-206-28	1 in 1 BOX		
2	NDC:13537-206-27	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL FILLING EFFECT FOUNDATION SPF 10 (OBSCURE 8) - BROWN

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-207
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC10H)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-207-30	1 in 1 BOX		
1	NDC:13537-207-29	30 mL in 1 BOTTLE		
2	NDC:13537-207-32	1 in 1 BOX		
2	NDC:13537-207-31	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL FILLING EFFECT FOUNDATION SPF 10 (OBSCURE 9) - BROWN

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-208
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 5 (UNII: 0TH5PCI0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-208-34	1 in 1 BOX		
1	NDC:13537-208-33	30 mL in 1 BOTTLE		
2	NDC:13537-208-36	1 in 1 BOX		
2	NDC:13537-208-35	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-200, 13537-201, 13537-202, 13537-203, 13537-204, 13537-205, 13537-206, 13537-207, 13537-208)

Revised: 12/2013

Ventura Corporation LTD