

**INTENSIVE COVER BLEMISH BALM- ethylhexyl methoxycinnamate, titanium dioxide, ethylhexyl salicylate, zinc oxide cream**  
**CMS LAB Inc.**

*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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**Intensive Cover Blemish Balm**

**Active ingredients**

Ethylhexyl Methoxycinnamate (6%)

Titanium Dioxide (4.044%)

Ethylhexyl Salicylate (2%)

Zinc Oxide (1.92%)

**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 when** skin is red, inflamed, irritated, or painful

**When using this product** do not apply on other parts of the body do not use on damaged or broken skin avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water do not apply directly to wound or open cut

**Stop use and ask a doctor if** Rash or irritation on skin develops and lasts

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**Directions**

- Apply the adequate amount onto the entire face at the last stage of your skin care routine.
- Apply liberally 15 minutes before sun exposure.
- Use a water-resistant sunscreen if swimming or sweating.
- Children under 6 months of age: ask a doctor

**Inactive ingredients**

WATER, CYCLOPENTASILOXANE, METHYLPROPANEDIOL, TRIETHOXYCAPRYLYLSILANE, TRIMETHYLSILOXYSILICATE, DIMETHICONE, TRISILOXANE, PHENYL TRIMETHICONE, DIISOSTEARYL MALATE, TALC, METHICONE, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, TOCOPHEROL, DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER, ALUMINUM HYDROXIDE, ALUMINUM STEARATE, CETYL ETHYLHEXANOATE, DISTEARDIMONIUM HECTORITE, IRON OXIDES(CI 77492), TRIETHOXYCAPRYLYLSILANE, CAPRYLYL GLYCOL, PALMITIC ACID, TRIHYDROXYSTEARIN, GLYCERYL CAPRYLATE, IRON OXIDES(CI 77499), TRIETHOXYCAPRYLYLSILANE, ETHYLHEXYLGLYCERIN, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, ROSE FLOWER OIL, JUNIPERUS MEXICANA OIL, HYDROGENATED LECITHIN, CERAMIDE 3 (CERAMIDE NP), SUCROSE STEARATE, CHOLESTEROL, CHOLESTERYL MACADAMIATE, STEARIC ACID, HYDROLYZED LUPINE PROTEIN, SACCHARIDE ISOMERATE

## Intensive Cover Blemish Balm

**Drug Facts**

Active Ingredient	Purpose
Ethylhexyl Methoxycinnamate (6%)	Sunscreen
Titanium Dioxide (4.044%)	Sunscreen
Ethylhexyl Salicylate (2%)	Sunscreen
Zinc Oxide (1.92%)	Sunscreen

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**Other information**

- Avoid storing product in direct sunlight.

**Inactive Ingredients**

WATER, CYCLOPENTASILOXANE, METHYLPROPANEDIOL, TRIETHOXYCAPRYLYLSILANE, TRIMETHYLSILOXYSILICATE, DIMETHICONE, TRISILOXANE, PHENYL TRIMETHICONE, DIISOSTEARYL MALATE, TALC, METHICONE, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, TOCOPHEROL, DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER, ALUMINUM HYDROXIDE, ALUMINUM STEARATE, CETYL

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## Intensive Cover Blemish Balm

SPF 30/PA++

A moisturizing blemish balm for perfect skin cover with weightless texture and long-lasting effect

**Intensive Cover Blemish Balm** sustains the perfect skin expression with moisture and weightless texture.

**DIRECTIONS:** Apply onto the entire face at the last stage of your skin care routine.

**NOTICE:** For external use only. Stop use if irritation occurs. Keep out of reach of children.

**INGREDIENTS:** WATER, TITANIUM DIOXIDE, CYCLOPENTASILOXANE, METHYLPROPANEDIOL, ETHYLHEXYL METHOXYCINNAMATE, DIMETHICONE, TRIMETHYLSILOXYSILICATE, PHENYL TRIMETHICONE, DIISOSTEARYL MALATE, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, CETYL ETHYLHEXANOATE, ETHYLHEXYL SALICYLATE, ZINC OXIDE, TRISILOXANE, DISTEARDIMONIUM HECTORITE, PEG-10 DIMETHICONE, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, ROSE FLOWER OIL, JUNIPERUS MEXICANA OIL, MAGNESIUM SULFATE, TALC, SYNTHETIC FLUORPHLOGOPITE, VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER, TOCOPHERYL ACETATE, POLYGLYCERYL POLYTRICINOLLATE, DIMETHICONE/VINYLTRIMETHYLSILOXYSILICATE CROSSPOLYMER, PALMITIC ACID, CAPRYLYL GLYCOL, TRIHYDROXYSTEARIN, ALUMINUM HYDROXIDE, TRIETHOXYCAPRYLYLSILANE, ALUMINUM STEARATE, GLY



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## INTENSIVE COVER BLEMISH BALM

ethylhexyl methoxycinnamate, titanium dioxide, ethylhexyl salicylate, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52554-1113
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.8 g in 30 mL
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	1.2132 g in 30 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.6 g in 30 mL
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.576 g in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	

CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
DIMETHICONE (UNII: 92RU3N3Y1O)
TRISILOXANE (UNII: 9G1ZW13R0G)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
TALC (UNII: 7SEV7J4R1U)
METHICONE (20 CST) (UNII: 6777U11MKT)
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)
TOCOPHEROL (UNII: R0ZB2556P8)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ALUMINUM STEARATE (UNII: U6XF9NP8HM)
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
FERRIC OXIDE RED (UNII: 1K09F3G675)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52554-1113-2	1 in 1 PACKAGE	11/01/2017	
1	NDC:52554-1113-1	30 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/01/2017	

**Labeler** - CMS LAB Inc. (557795012)

**Registrant** - CMS LAB Inc. (557795012)

Establishment			
Name	Address	ID/FEI	Business Operations
CMS LAB Inc.		557795012	relabel(52554-1113)

Establishment			
Name	Address	ID/FEI	Business Operations
Kolmar Korea Co., Ltd.		689512611	manufacture(52554-1113)