

**FACE VALUES - AM FACIAL MOISTURIZING BROAD SPECTRUM SPF30 SUNSCREEN-homosalate, octinoxate, octocrylene, zinc oxide lotion**

**Harmon Stores 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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**Harmon® FaceValues™ AM Facial Moisturizing Lotion**

**Active ingredient**

Homosalate 12.0%

Octinoxate 7.5%

Octocrylene 2.0%

Zinc Oxide 3.5%

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn
- If used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun

**Warnings**

**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 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use water resistant sunscreen if swimming or sweating
- Children under 6 months of age: ask a doctor
- **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15

or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses

### **Other Information**

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

### **Inactive ingredients**

water, niacinamide, behentrimonium methosulfate, cetyl alcohol, butylene glycol, cetearyl alcohol, glycerin, aluminum starch octenylsuccinate, boron nitride, propylene glycol, diazolidinyl urea, methylparaben, propylparaben, ceramide 3, ceramide 6- II, ceramide 1, phytosphingosine, cholesterol, sodium lauroyl lactylate, carbomer, xanthan gum, dimethicone, disodium EDTA, hyaluronic acid

### **Package/Label Principal Display Panel**

**Harmon® FaceValues™ AM Facial Moisturizing Lotion**

**Broad Spectrum SPF30 Sunscreen**

**moisturize**

**restore**

**maintain**

**moisturizes to help repair & restore skin's protective barrier**

**with Ceramides & UVA/UVB Protection**

**Non-comedogenic**

Compare Ours to the Active ingredients in CeraVe®  
AM Facial Moisturizing Lotion\*

3 Fl Oz (89 mL)

Distributed by  
Harmon Stores, Inc.  
650 Liberty Ave.  
Union, NJ 07083 USA  
©Harmon Stores, Inc.

Visit us at:  
[www.facevalues.com](http://www.facevalues.com)

Manufactured in Israel

8D121 B1 C1

\*This product is not manufactured or distributed by Coria Laboratories Ltd,  
owner of the registered trademark CeraVe™.



Label

## FACE VALUES - AM FACIAL MOISTURIZING BROAD SPECTRUM SPF30 SUNSCREEN

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| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:63940-121 |
| Route of Administration | TOPICAL        |                    |               |

| Active Ingredient/Active Moiety                                |                   |                 |
|----------------------------------------------------------------|-------------------|-----------------|
| Ingredient Name                                                | Basis of Strength | Strength        |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE        | 12 g in 100 mL  |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)   | OCTINOXATE        | 7.5 g in 100 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 2 g in 100 mL   |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)   | ZINC OXIDE        | 3.5 g in 100 mL |

| Inactive Ingredients                                                             |          |
|----------------------------------------------------------------------------------|----------|
| Ingredient Name                                                                  | Strength |
| WATER (UNII: 059QF0KO0R)                                                         |          |
| NIACINAMIDE (UNII: 25X51I8RD4)                                                   |          |
| BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)                                   |          |
| CETYL ALCOHOL (UNII: 936JST6JCN)                                                 |          |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA)                                               |          |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)                                           |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                                      |          |
| ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)                              |          |
| BORON NITRIDE (UNII: 2U4T60A6YD)                                                 |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                                              |          |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)                                             |          |
| METHYL PARABEN (UNII: A2I8C7HI9T)                                                |          |
| PROPYL PARABEN (UNII: Z8IX2SC1OH)                                                |          |
| CERAMIDE 3 (UNII: 4370DF050B)                                                    |          |
| CERAMIDE 6 II (UNII: F1X8L2B00J)                                                 |          |
| CERAMIDE 1 (UNII: 5THT33P7X7)                                                    |          |
| PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)                                              |          |
| CHOLESTEROL (UNII: 97C5T2UQ7J)                                                   |          |
| SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)                                      |          |
| CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L) |          |
| XANTHAN GUM (UNII: TTV12P4NEE)                                                   |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)                                                   |          |
| EDETATE DISODIUM (UNII: 7FLD91C86K)                                              |          |
| HYALURONIC ACID (UNII: S270N0TRQY)                                               |          |

| Packaging |                  |                     |                      |                    |
|-----------|------------------|---------------------|----------------------|--------------------|
| #         | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1         | NDC:63940-121-11 | 1 in 1 CARTON       |                      |                    |
| 1         |                  | 89 mL in 1 BOTTLE   |                      |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part352                                  | 11/15/2013           |                    |

**Labeler** - Harmon Stores Inc (804085293)

Revised: 11/2013

Harmon Stores Inc