# NARS SMOOTH AND PROTECT PRIMER- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone cream NARS Cosmetics

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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# NARS SMOOTH & PROTECT PRIMER

# **Drug Facts**

# **Active ingredients**

Avobenzone 2.5% Homosalate 10% Octisalate 5% Octocrylene 5% Oxybenzone 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 product is swallowed, get medical help or contact a Poison Control Center right away.

# **Directions**

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- 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 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

# **Inactive ingredients**

 $\label{lem:polymer} \begin{array}{l} \mbox{Dimethicone} \cdot \mbox{Methyl Trimethicone} \cdot \mbox{Dimethicone Crosspolymer} \cdot \mbox{Dimethicone} \\ \mbox{Crosspolymer} \cdot \mbox{Disteardimonium Hectorite} \cdot \mbox{Polymethylsilsesquioxane} \cdot \mbox{Silica} \cdot \\ \mbox{Trimethylsiloxysilicate} \cdot \mbox{HDI/Trimethylol Hexyllactone Crosspolymer} \cdot \mbox{PEG-10 Dimethicone} \cdot \\ \mbox{PEG/PPG-19/19 Dimethicone} \cdot \mbox{Hydrogenated Polyisobutene} \cdot \mbox{Tocopherol} \cdot \mbox{Vinyl} \\ \mbox{Dimethicone/Methicone Silsesquioxane Crosspolymer} \cdot \mbox{VP/Eicosene Copolymer} \cdot \mbox{Dipropylene Glycol} \cdot \\ \mbox{Water} \cdot \mbox{Lavandula Angustifolia (Lavender) Extract} \cdot \mbox{Dimethylmethoxy Chromanol} \cdot \mbox{Trisodium EDTA} \cdot \\ \mbox{Tin Oxide} \cdot \mbox{Mica} \cdot \mbox{Titanium Dioxide} \cdot \\ \end{array}$ 

# Other information

• protect this product in this container from excessive heat and direct sun

# Questions or comments?

Call toll free 1-888-788-NARS

# PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton

# **NARS**

SMOOTH & PROTECT PRIMER BROAD SPECTRUM SPF 50 SUNSCREEN

NET WT. 1 Oz. 30 mL

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  reapply at least
  every 2 hours
- **Sun Protection**

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 of 15 or higher and other sun protection measures including: limit time in the sun

# Drug Facts (continued)

# Inactive ingredients

Dimethicone · Methyl Trimethicone · Dimethicone/Vinyl Dimethicone Crosspolymer · Dimethicone Crosspolymer · Disteardimonium Hectorite · Polymethylsilsesquioxane · Silica · Trimethylsiloxysilicate · HDI/Trimethylol Hexyllactone Crosspolymer · PEG-10 Dimethicone · PEG/ PPG-19/19 Dimethicone ·

Hydrogenated Polyisobutene Tocopherol · Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer · VP/ Eicosene Copolymer · Dipropylene Glycol · Water · Lavandula Angustifolia (Lavender)

Extract · Dimethylmethoxy Chromanol · Trisodium EDTA · Tin Oxide · Mica · Titanium Dioxide ·

# Other information

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# Questions or comments?

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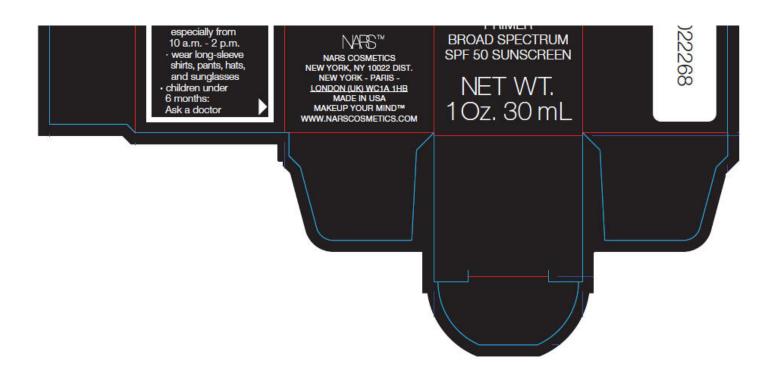


### SMOOTH & PROTECT PRIMER BROAD SPECTRUM SPF 50 SUNSCREEN

PERFECTING. PROTECTING. OIL-FREE, SKIN SMOOTHING COMPLEX BLURS THE LOOK OF PORES, FINE LINES AND WRINKLES, WHILE THE INVISIBLE DEFENSE TECH-NOLOGY WEIGHTLESSLY GLIDES ON TO DELIVER PROTECTION AGAINST UVA/ UVB RAYS AND POLLUTION. PROLONGS AND ENHANCES THE LOOK OF MAKEUP.

OIL-FREE. NON-COMEDOGENIC. DERMATOLOGIST TESTED.

DIRECTIONS FOR USE: AFTER SKINCARE AND BEFORE MAKEUP, APPLY A SMALL AMOUNT TO THE FACE OR DESIRED AREAS USING FINGERTIPS.



# NARS SMOOTH AND PROTECT PRIMER

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone cream

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:13734-157 |
| Route of Administration | TOPICAL        |                    |               |

| Active Ingredient/Active Moiety                                |                          |                    |  |
|--|--------------------------|--------------------|--|
| Ingredient Name  | <b>Basis of Strength</b> | Strength           |  |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE               | 741.7 mg in 30 mL  |  |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE               | 2967 mg in 30 mL   |  |
| OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) | OCTISALATE               | 1483.5 mg in 30 mL |  |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE              | 1483.5 mg in 30 mL |  |
| OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)   | OXYBENZONE               | 1483.5 mg in 30 mL |  |

| Inactive Ingredients  |          |  |
|---|----------|--|
| Ingredient Name   | Strength |  |
| DIMETHICO NE (UNII: 92RU3N3Y1O)   |          |  |
| METHYL TRIMETHICONE (UNII: S73ZQI0GXM)  |          |  |
| DIMETHICO NE/VINYL DIMETHICO NE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)         |          |  |
| DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) |          |  |
| DISTEARDIMO NIUM HECTO RITE (UNII: X687XDK09L)  |          |  |
| POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)                               |          |  |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)  |          |  |
| TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)                                |          |  |
| HEXAMETHYLENE DIISO CYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9 Y35Y9)   |          |  |
| PEG-10 DIMETHICO NE (600 CST) (UNII: 8 PR7V1SVM0)                                       |          |  |

| PEG/PPG-19/19 DIMETHICO NE (UNII: EHH90CO7TL)                                   |  |
|---|--|
| HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9 Y5EZ)                           |  |
| .ALPHATO COPHEROL (UNII: H4N855PNZ1)  |  |
| VINYL DIMETHICO NE/METHICO NE SILSESQUIO XANE CROSSPO LYMER (UNII: 9 NH1UDD2RR) |  |
| VINYLPYRROLIDONE/EICO SENE COPOLYMER (UNII: 035MV9S1C3)                         |  |
| DIPROPYLENE GLYCOL (UNII: E107L85C40)   |  |
| WATER (UNII: 059QF0KO0R)  |  |
| LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP (UNII: 9 YT4B71U8P)    |  |
| DIMETHYLMETHO XY CHROMANOL (UNII: XBH432G01F)                                   |  |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)   |  |
| MICA (UNII: V8A1AW0880)   |  |
| EDETATE TRISODIUM (UNII: 420 IP9 21MB)  |  |
| STANNIC OXIDE (UNII: KM7N50LOS6)  |  |

| P | Packaging        |   |                             |                           |
|---|------------------|---|-----------------------------|---------------------------|
| # | Item Code        | Package Description                                 | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1 | NDC:13734-157-60 | 1 in 1 CARTON                                       | 12/0 1/20 16                |                           |
| 1 |                  | 30 mL in 1 TUBE; Type 0: Not a Combination Product  |                             |                           |
| 2 | NDC:13734-157-61 | 1 mL in 1 PACKET; Type 0: Not a Combination Product | 12/0 1/20 16                |                           |

| Marketing Information   |  |                      |                    |
|-------------------------|--|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH NOT FINAL | part352                                  | 12/0 1/20 16         |                    |
|                         |  |                      |                    |

# Labeler - NARS Cosmetics (837363571)

Revised: 11/2018 NARS Cosmetics