

MALLY PERFECT PREP PORELESS PRIMER - avobenzone, octinoxate cream
MallyGirl, LLC

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.

mally Perfect Prep Poreless Primer Broad Spectrum SPF 15

DRUG FACTS

Active Ingredients

Avobenzone 2.0%

Octinoxate 7.5%

Purpose

Sunscreen

Sunscreen

Use

- 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.

For external use only

Do not use on damaged or broken skin.

Stop use and ask doctor if rash occurs.

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

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
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months: ask a doctor
- Sun Protection Measures. Spending time in the sun increases risk of skin cancer and early 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 10:00 a.m. - 2:00 p.m.
- Wear long sleeved shirts, pants, hats and sunglasses

Inactive Ingredients

Cyclopentasiloxane, Dimethicone/Vinyl Dimeticone Crosspolymer, Cyclomethicone, Hydrogenated

Vegetable Oil, C12-15 Alkyl Benzoate, Peg/Ppg-18/18 Dimethicone, Polymethylsilsesquioxane, Tocopheryl Acetate, Glycyrrhiza Glabra (Licorice) Root Extract, Silica, PEG-10 Rapeseed Sterol, Ceramide 2, Atelocollagen, Tribehenin, Palmitoyl Oligopeptide, Silica Dimethyl Silylate, Sodium Chondroitin Sulfate, Pentaerythrityl Tetraisoostearate, Ethylhexyl Palmitate, Distearidimonium Hectorite, Propylene Carbonate, Phenoxyethanol, Mica, Titanium Dioxide (CI 77891), Red 17 (CI 26100), Bismuth Oxychloride (CI 77163). Product made in the USA

Other Information

- Protect this product from excessive heat and direct sun.

Prices and availability are subject to change without notice.

Prices shown do not include shipping, handling, and applicable sales tax.

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Principal Display Panel

mally

Perfect Prep

Poreless Primer

with sunscreen

Broad Spectrum

SPF15

Drug Facts (continued)

- **Sun Protection Measures.**
Spending time in the sun increases risk of skin cancer and early 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 10:00 a.m. - 2:00 p.m.
 - Wear long sleeved shirts, pants, hats and sunglasses.

Inactive Ingredients

Cyclopentasiloxane, Dimethicone/Vinyl Dimethicone Crosspolymers, Octamethoxane, Hydrogenated Vegetable Oil, C12-15 Alkyl Benzoate, PEG/PPG-18/18 Dimethicone, Polymethylsiloxane, Tocopherol Acetate, Glycerin, Glycyrrhiza Glabra (Licorice) Root Extract, Silica, PEG-10 Repesent Sterol, Ceramide 2, Aminoacids, Trehalose, Palmitoyl Oligopeptide, Silica Dimethyl Silylate, Sodium Chondroitin Sulfate, Ethylhexyl Palmitate, Pentaerythrityl Tetraacetate, Disteartrimonium Hectorite, Propylene Carbonate, Phenoxethanol, Mica, Titanium Dioxide (CI 77891), Red 17 (CI 26108), Bismuth Oxychloride (CI 77163)
Product Made in USA.

Other Information

- Protect this product from excessive heat and direct sun.

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mally

Perfect Prep
poreless primer
with sunscreen
**BROAD SPECTRUM
SPF 15**

1.0 FL. OZ./30 ml

3341428-00

Drug Facts

Active Ingredients	Purpose
Azelaic Acid 2.0 %	Sunscreen
Octinoxate 7.5 %	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.

Stop use and ask doctor if rash occurs.

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

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

Directions

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- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- Children under 6 months: ask a doctor. ▶



Perfect Prep poreless primer with sunscreen

Drug Facts

Active Ingredients	Purpose
Avobenzone 2.0%	Sunscreen
Octinoxate 7.5%	Sunscreen

Use:
 • Helps prevent tanning. • 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

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Directions

• Apply liberally 15 minutes before sun exposure. • Use a water resistant sunscreen if swimming or sweating. • Reapply at least every 2 hours. • Children under 6 months: ask a doctor.
 • **Sun Protection Measures.** Spending time in the sun increases risk of skin cancer and early 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 10:00 a.m. - 2:00 p.m. • Wear long sleeved shirts, pants, hats and sunglasses.

INACTIVE INGREDIENTS

Cyclopentasiloxane, Dimethicone/Vinyl Dimethicone Crosspolymer, Cyclomethicone, Hydrogenated Vegetable Oil, C12-15 Alkyl Benzoate, Peg/Ppg-18/18 Dimethicone, Polymethylsilsesquioxane, Tocopheryl Acetate, Glycyrrhiza Glabra (Licorice) Root Extract, Silica, PEG-10 Ripseed Sterol, Cetamide 2, Asteocolagen, Tribehenin, Palmitoyl Oligopeptide, Silica Dimethyl Silylate, Sodium Chondroitin Sulfate, Ethylhexyl Palmitate, Pentacetylthyl Tetraosteardate, Disodiummonium Hectorite, Propylene Carbonate, Phenylethanol, Mica, Titanium Dioxide (CI 77891), Red 17 (CI 28100), Bismuth Oxystyrolate (CI 77165). Product made in USA.

Other Information

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MALLY PERFECT PREP PORELESS PRIMER

avobenzone, octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 119-1170
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Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.6 g in 30.0 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.25 g in 30.0 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CORN OIL (UNII: 8470G57WFM)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POLYETHYLENE GLYCOL 900 (UNII: UEP843BRCQ)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
PEG-10 RAPESEED STEROL (UNII: 258O76T85M)	
CERAMIDE 2 (UNII: C04977SRJ5)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSPOG0W)	
SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 17 (UNII: ND733RX3JN)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PENTAERYTHRITYL TETRAISO STEARATE (UNII: 9D7IK5483F)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76119-1170-1	1 in 1 BOX		
1		30 mL in 1 TUBE		
2	NDC:76119-1170-2	1 in 1 BOX		
2		28.3 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/29/2012	

Labeler - MallyGirl, LLC (167262554)

Revised: 7/2013

MallyGirl, LLC