

## **SLMD SKINCARE BY SANDRA LEE, M.D. - DARK SPOT FIX- hydroquinone cream SKIN PS BRANDS**

*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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### **SLMD Skincare by Sandra Lee, M.D. - Dark Spot Fix**

#### ***Drug Facts***

#### **Active Ingredient**

Hydroquinone 2.0%

#### **Purpose**

Skin Lightener

#### **Use**

For the gradual fading of dark (brownish) discolorations in the skin such as freckles, age and liver spots, or pigment in the skin that may occur in pregnancy or from the use of oral contraceptives.

#### **Warnings**

**For external use only.**

#### **When using this product**

- avoid contact with eyes
- some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor.

#### **Do not use**

- on children under 12 years of age unless directed by a doctor.

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

#### **Directions**

- Adults: Apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor. If no improvement is seen after 3 months of treatment, use of this product should be discontinued. Lightening effect of this product may not be noticeable when used on very dark skin
- **Children under 12 years of age:** do not use unless directed by a doctor
- Sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring
- **Sensitivity Test for a New User:** apply product sparingly to one or two small affected areas during first 3 days. If no discomfort occurs, follow directions above.

#### **Other information**

- store in a cool, dry place.

**Inactive Ingredients**

Water (Aqua), Butylene Glycol, Caprylic/Capric Triglyceride, Glycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Salicylic Acid, Kojic Acid, Squalane, Niacinamide, Sodium Hyaluronate, Phenoxyethanol, Xanthan Gum, Sodium Metabisulfite, Ethylhexylglycerin.

**Questions or comments?**

Visit us at [slmdskincare.com](http://slmdskincare.com)@slmdskincare

Distributed by Skin PS Brands

Culver City, CA 90232

**PRINCIPAL DISPLAY PANEL - 30 mL Jar Carton**

SLMD

SANDRA LEE MD

CREATED BY

DR.

PIMPLE

PoPPER

Dark Spot Fix

2% Hydroquinone

Skin Lightening Gel

1.0 fl. oz. / 30 mL

**LIGHTENS DARK SPOTS  
& HYPERPIGMENTATION**

**Drug Facts** (continued)

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[@slmdskincare](https://www.instagram.com/slmdskincare)

Distributed by Skin PS Brands  
Culver City, CA 90232  
Assembled in the USA

**SLMD**  
SANDRA LEE MD



**Dark Spot Fix**

2% Hydroquinone  
Skin Lightening Gel

1.0 fl. oz. / 30 mL

1029-2



### Dark Spot Fix

Dark Spot Fix is your triple threat for dark spots and hyperpigmentation. Skin lightening Hydroquinone helps to gradually fade dark marks caused by sun damage. Added Salicylic Acid helps to exfoliate and encourage new, fresh, even-toned skin, and Kojic Acid works to prevent future pigmentation from appearing. In a lightweight gel, it's the ultimate solution for skin lightening that targets dark spots due to acne, melasma, and sun exposure.

### How to use:

Apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor.

### Dermatologist formulated, skin approved

Created by pop culture's favorite dermatologist, SMD Skincare was formulated by Sandra Lee, MD to bridge the gap between the cluttered skincare aisle and a doctor's visit. You can trust each bottle will contain only the most effective ingredients, in formulas that your skin will love. Think of it as a trip to Dr. Pimple Popper's office, no appointment necessary.

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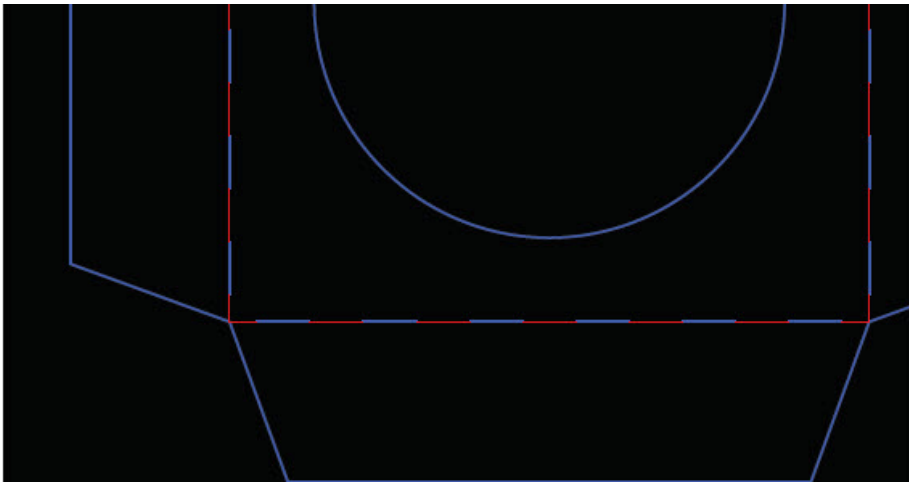
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## SLMD SKINCARE BY SANDRA LEE, M.D. - DARK SPOT FIX

hydroquinone cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73318-3994
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydroquinone (UNII: XV74C1N1AE) (Hydroquinone - UNII:XV74C1N1AE)	Hydroquinone	20 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
KOJIC ACID (UNII: 6K23F1TT52)	
SQUALANE (UNII: GW89575KF9)	
NIACINAMIDE (UNII: 25X51I8RD4)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:73318-3994-1	1 in 1 CARTON	05/15/2020	
1		30 mL in 1 JAR; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH NOT FINAL		part358 A	05/15/2020	

**Labeler - SKIN PS BRANDS (081085221)**

Revised: 2/2020

SKIN PS BRANDS