

**HUTTON KLEIN HK DERMATOLOGISTS SPF 40 MINERAL BASED FACIAL
SUNSCREEN TINTED- titanium dioxide, zinc oxide cream
Hutton, Kathleen MD**

DRUG FACTS

ACTIVE INGREDIENTS:

Titanium Dioxide 8%

Zinc Oxide 3.8%

PURPOSE:

Sunscreen

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 a doctor if rash occurs.

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

Keep out of the 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:
 - After 80 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours
- Children under 6 months: 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 am-2 pm
- Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS:

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide (CI77491), Lauryl PEG/PPG-18/18-Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- May stain some fabrics
- Cleanse thoroughly at nighttime
- PA+++

MANUFACTURED FOR:

Kathleen Hutton MD
Newport Beach, CA 92660

WWW.HUTTONKLEIN.COM

800-909-0060

Principal Display Panel - 53 g Bottle Label

HUTTON KLEIN

**HK
DERMATOLOGISTS**

SPF 40

Mineral Based
Facial Sunscreen

- Free of Chemical Sunscreens
- Water-Resistant (80 Minutes)
- Broad Spectrum
- Unscented
- Oil and PABA Free

Tinted

Net. Wt. 1.8 oz./ 53 g

DRUG FACTS (cont)

• 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 am-2 pm
- Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS: Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide (CI77491), Lauryl PEG/PPG-18/18-Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- May stain some fabrics
- Cleanse thoroughly at nighttime
- PA+++

MANUFACTURED FOR:

Kathleen Hutton MD
Newport Beach, CA 92660

WWW.HUTTONKLEIN.COM

800-909-0060

HUTTON KLEIN
HK
DERMATOLOGISTS

SPF 40

Mineral Based Facial Sunscreen

- Free of Chemical Sunscreens
- Water-Resistant (80 Minutes)
- Broad Spectrum
- Unscented
- Oil and PABA Free

Tinted

Net. Wt. 1.8 oz./ 53 g



DRUG FACTS

ACTIVE INGREDIENTS: Titanium Dioxide 8%
Zinc Oxide 3.8%

PURPOSE: Sunscreen
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 a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of the 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:
 - After 80 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours
- Children under 6 months:
Ask a doctor

HUTTON KLEIN HK DERMATOLOGISTS SPF 40 MINERAL BASED FACIAL SUNSCREEN TINTED

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81679-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	80 mg in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	38 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	
Cyclomethicone 6 (UNII: XHK3U310BA)	

Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Dimethicone 20 (UNII: H8YMB5QY0D)	
Dimethicone Crosspolymer (450000 MPA.S AT 12% in Cyclopentasiloxane) (UNII: UF7620L1W6)	
Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4CO0W6C5)	
Dimethiconol (2000 CST) (UNII: T74O12AN6Y)	
Brown Iron Oxide (UNII: 1N032N7MFO)	
Lauryl PEG/PPG-18/18 Methicone (UNII: ZJ5S27D9NX)	
Hydrogen Dimethicone (20 CST) (UNII: 12Z59IF64N)	
PEG-10 Dimethicone (600 CST) (UNII: 8PR7V1SVM0)	
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81679-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/17/2017	

Labeler - Hutton, Kathleen MD (792310955)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(81679-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(81679-203) , PACK(81679-203)

Revised: 12/2023

Hutton, Kathleen MD