

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE CICAPLAST BALM B5 UV
SKIN PROTECTANT SUNSCREEN SOOTHING THERAPEUTIC MULTI-PURPOSE
BROAD SPECTRUM SPF 50- dimethicone, homosalate, octisalate, octocrylene
and zinc oxide cream
L'Oreal USA Products Inc**

Drug Facts

Active ingredients

Dimethicone 1%

Homosalate 8%

Octisalate 5%

Octocrylene 5%

Zinc oxide 7%

Purpose

Skin protectant

Sunscreen

Sunscreen

Sunscreen

Sunscreen

Uses

- temporarily protects chapped or cracked skin
- 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

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating.
- **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
 - children under 6 months of age: Ask a doctor

Other information

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

Inactive ingredients

water, glycerin, propanediol, butyloctyl salicylate, petrolatum, panthenol, dimethicone, butyrospermum parkii (shea) butter, steareth-20, cellulose, ethylhexyl methoxycrylene, polymnia sonchifolia root juice, oryza sativa (rice) bran wax, steareth-2, sorbitan isostearate, madecassoside, triethoxycaprylylsilane, alpha-glucan oligosaccharide, mannose, ammonium polyacryloyldimethyl taurate, hydroxyacetophenone, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, hydroxyethylcellulose, caprylyl glycol, citric acid, trisodium ethylenediamine disuccinate, lactobacillus, maltodextrin, pentylene glycol, polyhydroxystearic acid, polysorbate 60, C12-22 alkyl acrylate/hydroxyethyl acrylate copolymer, chlorphenesin

Questions or comments?

1-888-LRP-LABO 1-888-577-5226

Monday - Friday (9 a.m. - 5 p.m. EST)

A SOOTHING THERAPEUTIC MULTI-PURPOSE CREAM WITH UV PROTECTION.

Suitable for cracked, chapped, chafed skin.



SUITABLE FOR SENSITIVE SKIN



RELIEVES DRY, CRACKED SKIN



PROTECTS SKIN BARRIER



HELPS PROTECT SKIN EXPOSED TO SUN



MINERAL & CHEMICAL SUN FILTERS



NON-COMEDOGENIC ■ FRAGRANCE-FREE ■ PARABEN-FREE



LA ROCHE-POSAY
LABORATOIRE DERMATOLOGIQUE

FOR CRACKED, CHAPPED, CHAFED SKIN

CICAPLAST BALM B5
SPF 50



CICAPLAST BALM B5 UV
DIMETHICONE SKIN PROTECTANT / SUNSCREEN
SOOTHING THERAPEUTIC MULTI-PURPOSE CREAM
BROAD SPECTRUM SPF 50

1.3 FL.OZ. - 40 ml

SHEA BUTTER + VITAMIN B5 + MADECASSOSIDE + TRIBIOMA™
WITH LA ROCHE-POSAY THERMAL SPRING WATER

Drug Facts

Active ingredients

Dimethicone 1%.....Skin protectant
Homosalate 8%.....Sunscreen
Octisalate 5%.....Sunscreen
Octocrylene 5%.....Sunscreen
Zinc oxide 7%.....Sunscreen

Uses

- temporarily protects chapped or cracked skin
- helps prevent sunburn

Purpose

Skin protectant
Sunscreen
Sunscreen
Sunscreen

Drug Facts (continued)

- 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

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Drug Facts (continued)

Directions

- For sunscreen use:
- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- 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
- children under 6 months of age: Ask a doctor

Other information

Protect the product in this container from excessive heat and direct sun

Drug Facts (continued)

Inactive ingredients

water, glycerin, propandiol, butylacetyl salicylate, petrolatum, panthenol, dimethicone, butyrospermum parkii (shea) butter, steareth-20, cellulose, ethylhexyl methoxycrylene, polymnia sonchifolia root juice, oriza sativa (rice) bran wax, steareth-2, sorbitan isostearate, madecassoside, triethoxycaprylsilane, alpha-glucan oligosaccharide, mannose, ammonium polyacrylate, dimethyl taurate, hydroxyacetophenone, hydroxyethyl acrylate/sodium acrylate/dimethyl taurate copolymer, hydroxyethylcellulose, caprylyl glycol, citric acid, triethanol ethylenediamine disuccinate, lactobacillus, maltodextrin, panthylene glycol, polyhydroxystearic acid, polyacrylate 60, C12-22 alkyl acrylate/hydroxyethylacrylate copolymer, chlorphenesin

Questions or comments?

1-888-LRP-LABO 1-888-571-5226

Monday - Friday 9 a.m. - 5 p.m. EST

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FIL Code V7087152/15

Distribution managed by La Roche-Posay agent distributors.

L'Oréal USA, Inc., 1001, 10 Hudson Fields, New York, NY 10001

Made in USA of US and/or imported ingredients





EXP

LOT

Drug Facts: Active ingredient: Dimethicone 1%. **Purpose:** Skin protectant. **Active ingredients:** Homosalate 8%, Octisalate 5%, Octocrylene 5%, Zinc oxide 7%. **Purpose:** Sunscreen. **Uses:** Temporarily protects chapped or cracked skin. Helps prevent sunburn. **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 a water resistant sunscreen if swimming or sweating. **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. Children under 6 months of age: Ask a doctor. **Other information:** Protect the product in this container from excessive heat and direct sun. **Questions or comments?** 1-888-LRP-LABO 1-888-577-5226 Monday-Friday (9 a.m.-5 p.m. EST)

Distribution reserved to La Roche-Posay agreed distributors.

La Roche-Posay LLC, 10 Hudson Yards, New York, NY 10001

Made in USA of US and/or Imported Ingredients

www.laroche-posay.us

40 ml / 1.35 FL.OZ.



LA ROCHE-POSAY
LABORATOIRE DERMATOLOGIQUE

CICAPLAST BALM B5 UV

DIMETHICONE SKIN PROTECTANT / SUNSCREEN

SOOTHING THERAPEUTIC MULTI-PURPOSE CREAM

BROAD SPECTRUM SPF 50

SHEA BUTTER + VITAMIN B5 + MADECASSOSIDE + TRIBIOMA™

WITH LA ROCHE-POSAY THERMAL SPRING WATER

LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE CICAPLAST BALM B5 UV SKIN PROTECTANT SUNSCREEN SOOTHING THERAPEUTIC MULTI-PURPOSE BROAD SPECTRUM SPF 50

dimethicone, homosalate, octisalate, octocrylene and zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:82046-992

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (ETHYLHEXYL SALICYLATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	10 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPANEDIOL (UNII: 5965N8W85T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
PETROLATUM (UNII: 4T6H12BN9U)	
PANTHENOL (UNII: WW9CM0O67Z)	
BUTYROSPERMUM PARKII (SHEA) BUTTER (UNII: K49155WL9Y)	
STEARETH-20 (UNII: L0Q8IK9E08)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
POLYMNIA SONCHIFOLIA ROOT JUICE (UNII: M9S7HX36CT)	
ORYZA SATIVA (RICE) BRAN (UNII: R60QEP13IC)	
STEARETH-2 (UNII: V56DFE46J5)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
MADECASSOSIDE (UNII: CQ2F5O6YIY)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALPHA-GLUCAN OLIGOSACCHARIDE (UNII: S95658MI3W)	
MANNOSE (UNII: PHA4727WTP)	
AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (UNII: F01RIY4371)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
HYDROXYETHYLCELLULOSE (UNII: T4V6TWG28D)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CITRIC ACID (UNII: 2968PHW8QP)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
LACTOBACILLUS (UNII: 5307V7XW8I)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82046-992-01	1 in 1 CARTON	04/01/2024	

1		40 mL in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020		04/01/2024	

Labeler - L’Oreal USA Products Inc (002136794)

Establishment			
Name	Address	ID/FEI	Business Operations
L'OREAL USA PRODUCTS, INC.		624244349	manufacture(82046-992)