

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE CICAPLAST BALM B5
SOOTHING THERAPEUTIC MULTIPURPOSE- dimethicone cream
L'Oreal USA Products Inc**

Drug Facts

Active ingredient

Dimethicone 1%

Purpose

Skin protectant

Uses

- temporarily protects and helps relieve chafed, chapped or cracked skin
- helps protect from the drying effects of wind and cold weather
- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps seal out wetness

Warnings

For external use only

Do not use

- on deep or puncture wounds
- animal bites
- serious burns

When using this product

do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply as needed

For diaper rash:

- change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry
- apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other information

- store at room temperature

Inactive ingredients

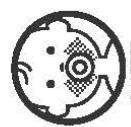
water, hydrogenated polyisobutene, glycerin, butyrospermum parkii (shea) butter, panthenol, aluminum starch octenylsuccinate, butylene glycol, propanediol, cetyl PEG/PPG-10/1 dimethicone, trihydroxystearin, zinc gluconate, madecassoside, manganese gluconate, silica, aluminum hydroxide, magnesium sulfate, disodium EDTA, copper gluconate, citric acid, acetylated glycol stearate, polyglyceryl-4 isostearate, tocopherol, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, sodium benzoate, phenoxyethanol, chlorhexidine digluconate, titanium dioxide

Questions or comments?

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

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

A SOOTHING THERAPEUTIC CREAM WITH MULTI-PURPOSE PROPERTIES.
Suitable for adults, children and babies. For areas such as:



CHAFED, CHAPPED SKIN



CRACKED, DRY HANDS AND ELBOWS



DRY FACE, NOSE, LIPS



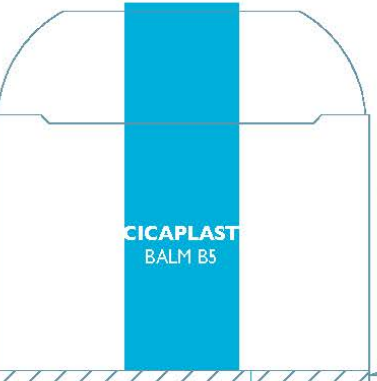
ROUGH, DRY KNEES, LEGS, AND FEET



DIAPER RASH



FOR CRACKED, CHAPPED, CHAFED SKIN



CICAPLAST
BALM B5

CICAPLAST BALM B5
with La Roche-Posay Thermal Spring Water

SOOTHING THERAPEUTIC
MULTI-PURPOSE CREAM
DIMETHICONE SKIN PROTECTANT

Temporarily protects and helps relieve cracked, chapped, chafed skin
SHEA BUTTER • VITAMIN B5 • MADECASSOSIDE

Antibiotic-free. Steroid-free
Adults, Children, Babies

LA ROCHE-POSAY
LABORATOIRE DERMATOLOGIQUE

40 ml / 1.35 FL.OZ. Made in France

FOR: Cracked, chapped, chafed, dry skin. Suitable for adults, children, and babies, as young as 1 month.
PROPERTIES: Cicaplast Balm B5 is a multi-purpose cream for the face and body. Specially formulated with Vitamin B5 (panthenol), Madecassoside, and a unique mineral complex (Copper, Zinc, Manganese) to help dry skin feel soothed, while Dimethicone temporarily protects chapped, cracked and chafed skin. Helps protect from the drying effects of wind and cold weather, and helps treat and prevent diaper rash. Ultra-softening texture, non-greasy finish.
RESULTS: Sensitive skin feels soothed. Skin comfort and hydration levels restored.
DERMATOLOGIST TESTED FOR SAFETY. Steroid-free. Antibiotic-free. Fragrance-free. Paraben-free. Lanolin-free. Allergy tested.
Non-comedogenic. Tested on sensitive skin.

Drug Facts

Active ingredient Dimethicone 1%
Purpose Skin protectant
Uses Temporarily protects and helps relieve cracked, chapped or chafed skin

Drug Facts (continued)

Helps protect from the drying effects of wind and cold weather
Helps treat and prevent diaper rash
Protects chafed skin due to diaper rash and helps seal out wetness

Drug Facts (continued)

Warnings For external use only
Do not use on deep or puncture wounds • animal bites • serious burns
When using this product Do not get into eyes
Stop use and ask a doctor if condition worsens
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply as needed
For diaper rash:
• change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry
• apply cream liberally as often as necessary, with each diaper change especially at bedtime or any time when exposure to wet diapers may be prolonged

Drug Facts (continued)

Other information Store at room temperature
Inactive ingredients water, hydrogenated polybutene, dimethicone, glycerin, butyrospermum (shea) butter, panthenol, aluminum starch octenylsuccinate, butylene glycol, propylene glycol, PEG/PPG-10/1 dimethicone trihydroxystearin, zinc gluconate, madecassoside, manganese gluconate, silica, aluminum hydroxide, magnesium sulfate, disodium EDTA, copper gluconate, citric acid, acetylated glycol stearate, polyglyceryl-4 isostearate, tocopherol, penterythrityl tetra-d-4-butyl hydroxyhydroximate sodium benzoate, phenoxyethanol, chloroform, titanium dioxide

Questions or comments?

Made in France
Distribution reserved to La Roche-Posay agreed distributors
La Roche-Posay LLC, 40 Hilsen Yank, New York, NY 10001
Monday - Friday (9 a.m. - 5 p.m. EST)
Call 800 720 2220 La Roche-Posay, France
TSA 75000 USCMA ST OUDER CEDEX FR
800990 17



661320899212

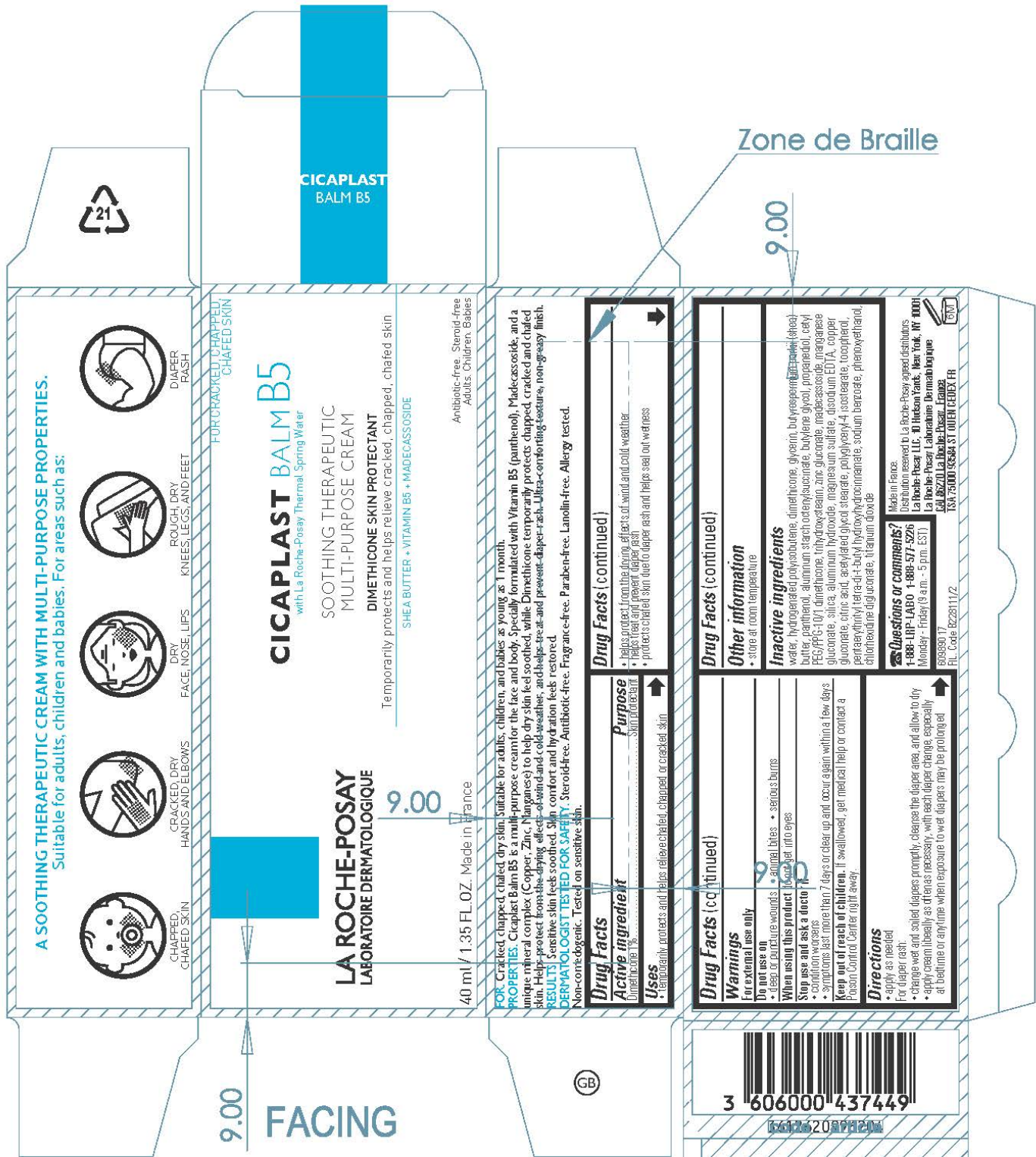
Zone de Braille

9.00

9.00

FACING





LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE CICAPLAST BALM B5 SOOTHING THERAPEUTIC MULTIPURPOSE

dimethicone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-744
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
SHEA BUTTER (UNII: K49155WL9Y)	
PANTHENOL (UNII: WW9CM0O67Z)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
MADECASSOSIDE (UNII: CQ2F5O6YIY)	
MANGANESE GLUCONATE (UNII: 9YY2F980SV)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
COPPER GLUCONATE (UNII: RV823G6G67)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ACETYLATED GLYCOL STEARATE (UNII: K71M6R9N7E)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-744-01	1 in 1 CARTON	03/15/2021	
1		40 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-744-02	1 in 1 CARTON	03/15/2021	
2		3 mL in 1 TUBE; Type 0: Not a Combination Product		

3	NDC:49967-744-03	1 mL in 1 PACKET; Type 0: Not a Combination Product	03/15/2021	
4	NDC:49967-744-04	1 in 1 CARTON	01/01/2023	
4		100 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	M016	03/15/2021	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetique Active Production		282658798	manufacture(49967-744)

Establishment

Name	Address	ID/FEI	Business Operations
L'OREAL USA PRODUCTS, INC.		624244349	pack(49967-744)

Revised: 12/2023

L'Oreal USA Products Inc