

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE CICAPLAST BALM B5  
THERAPEUTIC MULTIPURPOSE- dimethicone cream  
Cosmetique Active Production**

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**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**

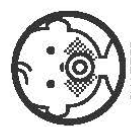
water, hydrogenated polyisobutene, glycerin, butyrospermum parkii (shea) butter, panthenol, aluminum starch octenylsuccinate, butylene glycol, propanediol, cetyl PEG/PPG-10/1 dimethicone, trihydroxystearin, zinc gluconate, madecassoside, manganese gluconate, silica, aluminum hydroxide, magnesium sulfate, 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**  
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. Help protect from the drying effects of wind and cold weather, and helps treat and prevent diaper rash. Ultra-comforting texture, non-greasy finish.  
**RESULTS:** Sensitive skin feels soothed. Skin comfort and hydration feels 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 (continued)**

**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 • 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 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-di-4-butyl hydroxydihydroximate 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 Hickson Yard, New York, NY 10001**  
Monday - Friday (9 a.m. - 5 p.m. EST)  
Call 800 720 2220 La Roche-Posay, France  
TSA: 75000 95384 ST OMER CEDEX FR  
800990 17  
FL Code BZ28117Z



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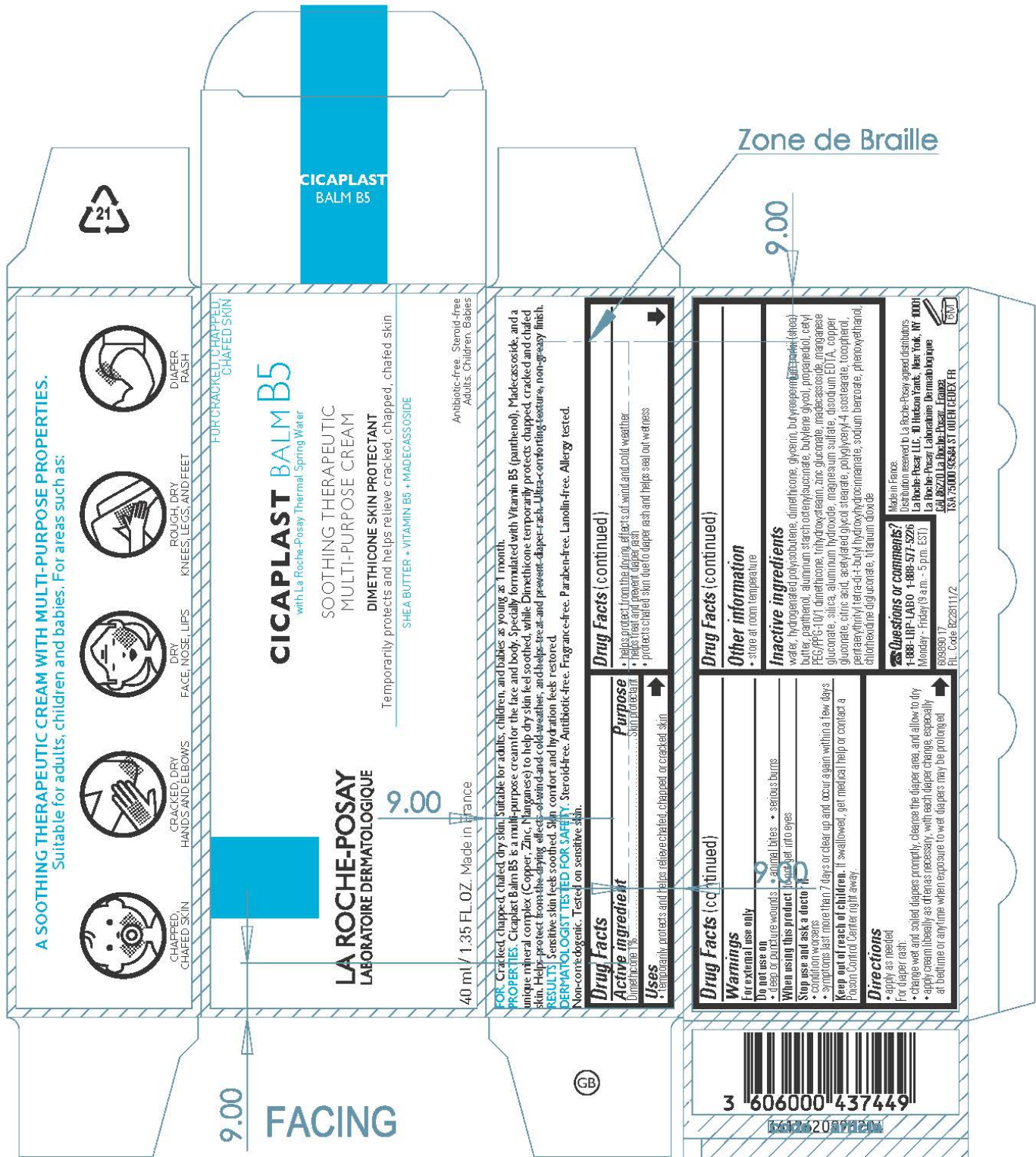
Zone de Braille

9.00

9.00

FACING





# LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE CICAPLAST BALM B5 THERAPEUTIC MULTIPURPOSE

dimethicone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69625-743
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69625-743-01	1 in 1 CARTON	03/15/2021	
1		40 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69625-743-02	1 in 1 CARTON	03/15/2021	
2		3 mL in 1 TUBE; Type 0: Not a Combination Product		

3	NDC:69625-743-03	1 mL in 1 PACKET; Type 0: Not a Combination Product	03/15/2021	
4	NDC:69625-743-04	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** - Cosmetique Active Production (282658798)

## Establishment

Name	Address	ID/FEI	Business Operations
Cosmetique Active Production		282658798	manufacture(69625-743)

## Establishment

Name	Address	ID/FEI	Business Operations
L'OREAL USA PRODUCTS, INC.		624244349	pack(69625-743)

Revised: 12/2023

Cosmetique Active Production