

**TENDER MOMENTS BABY BOTTOM BALM- zinc oxide, dimethicone cream**  
**JAFRA COSMETICS INTERNATIONAL**

*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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**Tender moments Baby Bottom Balm**

Active Ingredients: Zinc Oxide/CI77947, Dimethicone

Soothing balm for baby's tender bottom that helps treat and prevent diaper rash.

No Such information

If condition worsens or does not improve within 7 days, consult a doctor.

For external use only. Avoid contact with eyes

To use: With each diaper change, cleanse the diaper area and allow to dry. Apply baby bottom balm liberally, especially when exposure to wet diapers may be prolonged.

Other ingredients: Water/aqua, petrolatum, Diisostearoyl Polyglyceryl-3 Diisostearate, Ethylhexyl stearate, Avena Sativa (Oat) Kernel Extract, Aloe Barbadensis Oil, Butyrospermum Parkii (Shea Butter) Fruit, Panthenol, Glycine Soja (Soybean) Oil. Cetyl Dimethicone, Magnesium Sulfate, Beeswax/Cera Alba, Butylene Glycol, DMDM Hydantoin, PEG-4 Laurate, Iodopropynyl Butylcarbamate.

## BALSAM FÜR DEN BABYPO BALSAMO ANTIARROSSAMENTO BAMBINI

A soothing balm for baby's tender bottom that helps treat and prevent diaper rash. Specially formulated to protect skin while allowing it to breathe.

Contains natural Shea Butter and Oat extracts to help soothe irritated skin and Aloe Vera and Provitamin B5 to moisturize. Fragrance-free. Clinically, allergy, irritancy, and pediatrician-tested.

**To use:** With each diaper change, cleanse the diaper area and allow to dry. Apply Baby Bottom Balm liberally and as often as necessary, especially when exposure to wet diapers may be prolonged.

**Warnings:** For external use only. Avoid contact with eyes. If condition worsens or does not improve within 7 days, consult a doctor.

Crema suavizante que ayuda a minimizar las molestias causadas por las rozaduras.

Especialmente formulada para ayudar a proteger la piel, permitiendo que ésta respire. Contiene Manteca de Karité y extracto de Avena que ayudan a suavizar la piel irritada del bebé, además de Aloe Vera y Provitamina B5 que humectan. Clínicamente probada en alergia e irritación.

**Instrucciones de Uso:** Aplique en cada cambio de pañal después de la limpieza una vez que la piel del bebé esté seca y especialmente cuando la piel haya estado expuesta a un pañal húmedo por un período prolongado.

**Precaución:** Sólo para uso externo. Evite el contacto con los ojos. Si las molestias persisten después de 7 días, consulte a su médico. Úsese bajo la supervisión de un adulto.

**Avvertenze:** Solo per uso esterno. Evitare il contatto con gli occhi.

Made in Mexico for:

Jafra Cosmetics International, Inc.

Westlake Village, CA 91361

[www.JAFRA.com](http://www.JAFRA.com)

Hecho en México para:

Distribuidora Comercial Jafra, S.A. de C.V.

Blvd. Adolfo López Mateos 515,

Col. Tlacopac, México, D. F., 01040



Jafra y Tender Moments son Marcas Registradas en México;

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**LOS ANGELES - ZURICH - MUNICH**  
**MEXICO CITY - MILAN**



**ACTIVE INGREDIENTS:** Zinc Oxide/CI 77947, Dimethicone.

**OTHER INGREDIENTS:** Water/Aqua, Petrolatum, Isopropyl Palmitate, Diisostearoyl Polyglyceryl-3 Diisostearate, Ethylhexyl Stearate, Avena Sativa (Oat) Kernel Extract, Aloe Barbadensis Oil, Butyrospermum Parkii (Shea Butter) Fruit, Panthenol, Glycine Soja (Soybean) Oil, Cetyl Dimethicone, Magnesium Sulfate, Beeswax/Cera Alba, Butylene Glycol, DMDM Hydantoin, PEG-4 Laurate, Iodopropynyl Butylcarbamate.

**INGREDIENTES:** Agua, Oxido de Cinc, Petrolato, Palmitato de Isopropilo, Diisoestearato de Diisoestearoil Poliglicerilo-3, Estearato de Octilo, Dimeticona, Extracto de Avena (Avena Sativa), Aceite de Aloe Barbadensis, Manteca de Karité (Butyrospermum Parkii), Pantenol, Aceite de Soya (Glycine Soja), Cetil Dimeticona, Sulfato de Magnesio, Cera de Abeja, Butilenglicol, Hidantoína DMDM, PEG-4 Laurato, Yodopropinil Butilcarbamato.



Tender Moments

Baby Bottom Balm

Crema Suavizante para Rozaduras

Jafra

50 ml 1.7 fl. oz



## Tender Moments

**BABY BOTTOM BALM  
CREMA SUAVIZANTE  
PARA ROZADURAS**

JAFRA

50 ml e 1.7 FL OZ (US)



Schützt den Babypo vor gereizter, geröteter, wunder Haut und hält die Feuchtigkeit ab.

Duftfrei. Klinisch und von Kinderärzten auf Allergien und Unverträglichkeiten getestet.

Reinigen Sie den Babypo bei jedem Wechsel der Windel und lassen die Haut trocknen. Tragen Sie den Balsam für den Babypo großzügig und so häufig wie nötig auf, besonders, wenn das Baby länger eine nasse Windel getragen hat.

Aiuta a proteggere la pelle arrossata e irritata a causa dei pannolini e aiuta a mantenere la pelle asciutta.

Privo di fragranza. Clinicamente testato contro allergia e irritazione.

Ad ogni cambio di pannolini, detergere la pelle e lasciarla asciugare. Applicare il prodotto abbondantemente e ogni volta che sia necessario, specialmente quando la pelle è rimasta a lungo bagnata o irritata.

**TENDER MOMENTS BABY BOTTOM BALM**

zinc oxide, dimethicone cream

## Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:68828-095 |
| Route of Administration | TOPICAL        |                    |               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength       |
|--|-------------------|----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)   | ZINC OXIDE        | 10 g in 100 mL |
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE       | 2 g in 100 mL  |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R)                               |          |
| PETROLATUM (UNII: 4T6H12BN9U)                          |          |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)                 |          |
| OAT (UNII: Z6J799EAJK)                                 |          |
| PANTHENOL (UNII: WV9CM0O67Z)                           |          |
| SOYBEAN OIL (UNII: 241ATL177A)                         |          |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)                 |          |
| MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB) |          |
| WHITE WAX (UNII: 7G1J5DA97F)                           |          |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA)                     |          |
| DMDM HYDANTOIN (UNII: BYR0546TOW)                      |          |
| PEG-4 LAURATE (UNII: AYF4VM3N1Z)                       |          |
| IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)         |          |

## Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:68828-095-01 | 1 in 1 BOX   | 06/07/2012           |                    |
| 1 |                  | 50 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 mono graph not final | part352                                  | 06/07/2012           |                    |

**Labeler** - JAFRA COSMETICS INTERNATIONAL (041676479)

**Registrant** - JAFRA COSMETICS INTERNATIONAL (041676479)

## Establishment

| Name                              | Address | ID/FEI    | Business Operations    |
|-----------------------------------|---------|-----------|------------------------|
| Jafra Manufacturing, S.A. de C.V. |         | 814732061 | manufacture(68828-095) |

