

**TENDER MOMENTS DELICATE BABY DIAPER RASH BALM- dimethicone,zinc oxide cream**

**Jafra Cosmetics International, Inc.**

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**Tender Moments Delicate Baby Diaper Rash Balm**

***Active Ingredients***

Dimethicone 2.0%, Zinc Oxide 10.0%

***Purpose***

Skin Protectant

***Uses***

- Helps treat and prevent diaper rash
- Protects chafed skin due to diaper rash and helps seal out wetness

***Warnings***

**For external use only**

**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 in a few days

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

- 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

***Inactive Ingredients***

Water/Aqua, Petrolatum, Isopropyl Palmitate, Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate, Ethylhexyl Stearate, Cetyl Dimethicone, Magnesium Sulfate, Beeswax/Cera Alba, Butyrospermum Parkii (Shea Butter), Panthenol, Butylene Glycol, Avena Sativa (Oat) Kernel Extract, DMDM Hydantoin, Glycine Soja (Soybean) Oil, Aloe Barbadensis Oil

**Product label**

TMRN-018

JAFRA

LABEL-TM DELICATE  
BABY BOTTOM BALM  
27.OCT.23

MPVG

FINAL ARTWORK

TMRN-010 REV.3 WITH OTC OVERLABEL  
IS TMRN-018

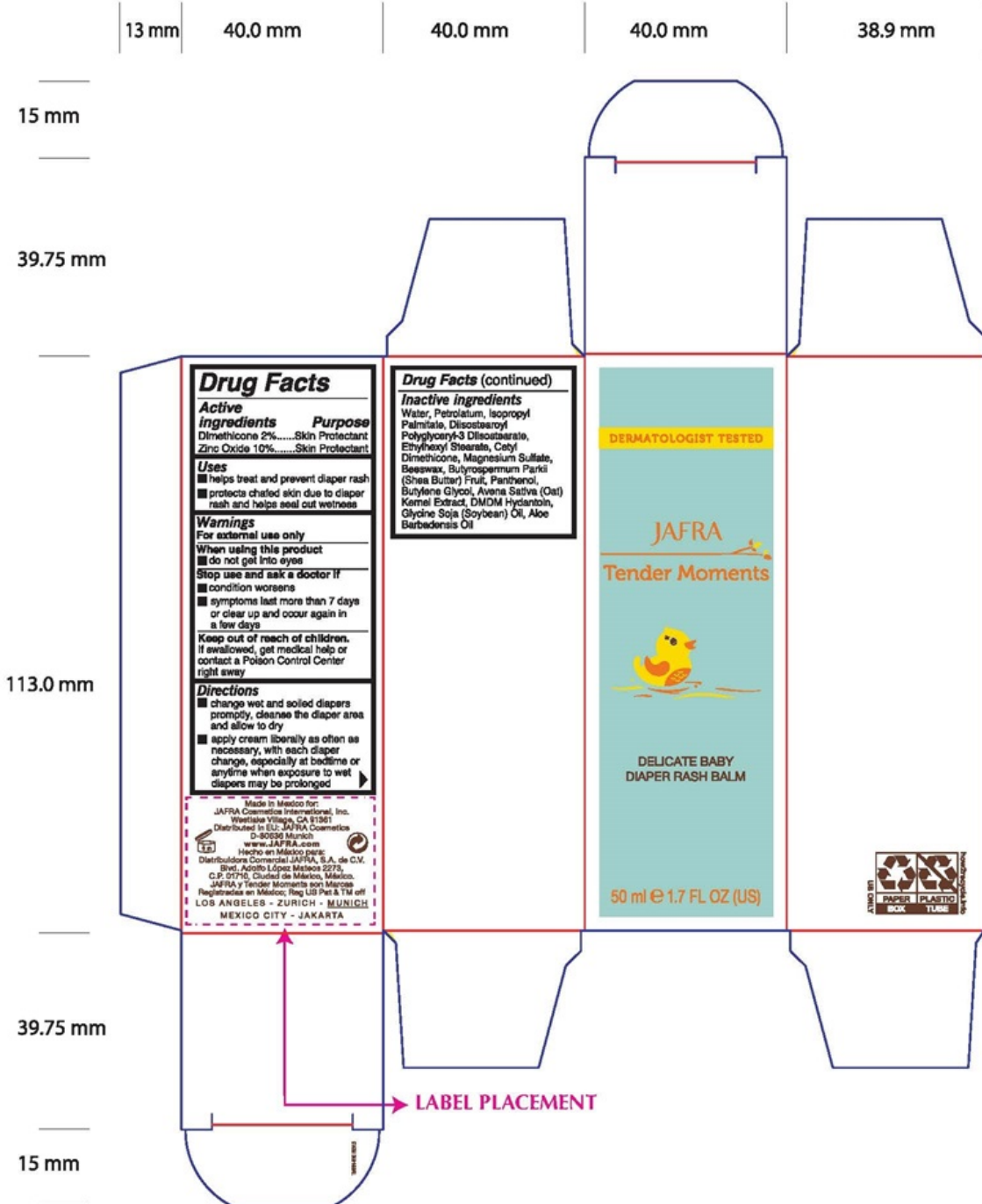
PMS Only for reference  
(Match against physical sample)



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DO NOT PRINT



LABEL PLACEMENT

TENDER MOMENTS DELICATE BABY DIAPER RASH BALM

dimethicone,zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68828-700
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2 g in 100 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	10 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>DIISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE</b> (UNII: G3232Z5S2O)	
<b>ETHYLHEXYL STEARATE</b> (UNII: EG3PA2K3K5)	
<b>CETYL DIMETHICONE 25</b> (UNII: U4AS1BW4ZB)	
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>PANTHENOL</b> (UNII: WW9CM0O67Z)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>OAT</b> (UNII: Z6J799EAJK)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-700-01	1 in 1 CARTON	12/29/2021	
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 Monograph Drug	M016	12/29/2021	

**Labeler** - Jafra Cosmetics International, Inc. (041676479)

## Establishment

Name	Address	ID/FEI	Business Operations
Distribuidora Comercial Jafra, S.A. de C.V.		951612777	manufacture(68828-700)

Revised: 12/2023

Jafra Cosmetics International, Inc.