

BABY MAGIC MEDICATED PATTY CAKE - zinc oxide cream
Naterra International INC.

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.

Baby Magic Medicated Patty Cake

Active Ingredient : Zinc Oxide (28%)

Uses: Helps treat and prevent diaper rash. Protects minor skin irritation associated with diaper rash and helps protect from wetness.

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

Warnings; For external use only

Direction

Change wet and soiled diapers promptly; cleanse diaper area and allow to dry

Apply product liberally as often as necessary, with each diaper change specially at bedtime or anytime when exposure to wet diapers may be prolonged. Swipe disposable cotton round applicator across Medicated Patty Cake.

Apply baby powder on baby's bottom and other areas that can use powder and are susceptible to irritating friction. For sanitation purpose, never touch a cotton round applicator that has been on the baby's bottom back onto the powder.

Dispose of cotton round applicator after each use.

Allantoin ,Beeswax, Benzoic Acid, BHT, C12-15 Alkyl Benzoate, Copernicia Cerifera (Carnauba Wax) , Euphorbia Cerifera (Candellila) Wax, Fragrance , Glycereth-2 Cocoate , Hexyl Carprate , Lauryl Lysine , Nylon-12 , Ozokerite Wax, PEG-40 Stearate, Phenyl Trimethicone, Polymethylmethacrylate, Silica, Stearyl Alcohol, Titanium Dioxide, Tocopheryl Acetate

**U.S. Patented
Dustless Baby Powder**

Baby Magic

Medicated Patty Cake[®]

**Medicated
Cream-to-Powder**

Medicated Patty Cake, a dustless baby powder, helps treat and prevent diaper rash, while giving your baby a powder smooth skin and a fresh baby scent.

Dustless baby powder, the new way to protect your baby against:

- Diaper Rash
- Chafed Skin
- Wetness
- Minor Irritation

Why Medicated Patty Cake is better than leading diaper treatments:

- Non-greasy
- No parabens
- No petrolatum
- Fresh baby scent
- No mineral oil
- No-Mess Application

Drug Facts	
Active Ingredient: Zinc Oxide 25%	Purpose: Skin Protectant
Uses: • Helps treat and prevent diaper rash. Protects minor skin irritation associated with diaper rash and helps protect from 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 within a few days	
Do not use on: • Broken skin	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	
Directions: • Change wet or soiled diapers promptly, cleanse the diaper area, and allow to dry. • Apply product liberally as often as necessary, with each diaper change especially at bedtime or anytime when exposure to wet diapers may be prolonged. Swipe disposable cotton round applicator across Medicated for Diaper Rash Cream to Powder. Apply product on baby's bottom and other areas that are susceptible to irritating friction. For sanitation purposes, never touch a cotton round applicator that has been on the baby's bottom back onto the compact. Dispose of cotton round applicator after each use.	
Other Information: • Store at Room Temperature (59-86° F)	
Inactive Ingredients: Hexyl Caprate, C12-15 Alkyl Benzoate, Polyethylene Methylsiloxane, Nylon-12, PEG-40 Stearate, Octocrylene, Silica, L-Ascorbyl Tetrahydro Palmitate (Carvedo™) Wax, Capramide Ceraflin (Ceraflin™) Wax, Fragrance, Benzoin, Stearyl Alcohol, Phenyl Trimethylammonium Chloride, Tocopherol Acetate, Titanium Dioxide, Glyceryl-2-Cocostearate, Benzoic Acid, BHT	
Questions? Visit www.babymagic.com or call 1-888-988-2967, M-F	

Distributed by: **Rotem International, Inc.**
Houma, LA 70306

MADE IN THE USA

725103804 11 0 75371 05100 5

Enter section text here

BABY MAGIC MEDICATED PATTY CAKE

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45765-5100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	2.75 g in 11 g

Inactive Ingredients

Ingredient Name	Strength
Allantoin (UNII: 344S277G0Z)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CANDELILLA WAX (UNII: WL0328HX19)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
HEXYL DECANOATE (UNII: D2D42X538B)	
LAUROYL LYSINE (UNII: 113171Q70B)	
NYLON-12 (UNII: 446U8J075B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45765-5100-0	11 g in 1 TRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	01/01/2012	

Labeler - Naterra International INC. (879056786)

Revised: 1/2012

Naterra International INC.