

**LITTLE BUBS DIAPER- zinc oxide cream**  
**LITTLE BUBS COMPANY PTY LTD**

*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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**LITTLE BUBS DIAPER BRUSH AND CREAM**

**ACTIVE INGREDIENT**

ZINC OXIDE 15.25%

**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 AVOID CONTACT WITH THE EYES
- STOP USE AND ASK A DOCTOR IF CONDITION WORSENS OR DOES NOT IMPROVE AFTER 7 DAYS
- KEEP OUT OF REACH OF CHILDREN TO PREVENT ACCIDENTAL INGESTION
- IF SWALLOWED, SEEK MEDICAL HELP OR CALL POISON CONTROL CENTER IMMEDIATELY
  
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**DIRECTIONS**

- REMOVE SEAL FROM CONTAINER PRIOR TO USE
- CHANGE WET AND SOILED DIAPER IMMEDIATELY
- CLEANSE THE DIAPER AREA AND ALLOW TO DRY
- PUSH BUTTON TO ACCESS CREAM. SWEEP THE APPLICATOR BRUSH MOVING THE BRISTLES BACK AND FORTH IN A SEMI-CIRCLE LOADING CREAM ONTO YOUR DIAPER BRUSH AS REQUIRED
- APPLY CREAM LIBERALLY AND AS OFTEN AS NECESSARY WITH EACH DIAPER CHANGE AND ESPECIALLY WHEN EXPOSED TO WET DIAPERS FOR A PROLONGED PERIOD OF TIME, SUCH AS BEDTIME
- RETURN YOUR DIAPER BRUSH TO ITS CENTER CAVITY AND CLOSE THE LID. ONCE BABY HAS BEEN SAFELY SET DOWN, USE A BABY WIPE OR TISSUE TO SPOT CLEAN YOUR DIAPER BRUSH IF REQUIRED.

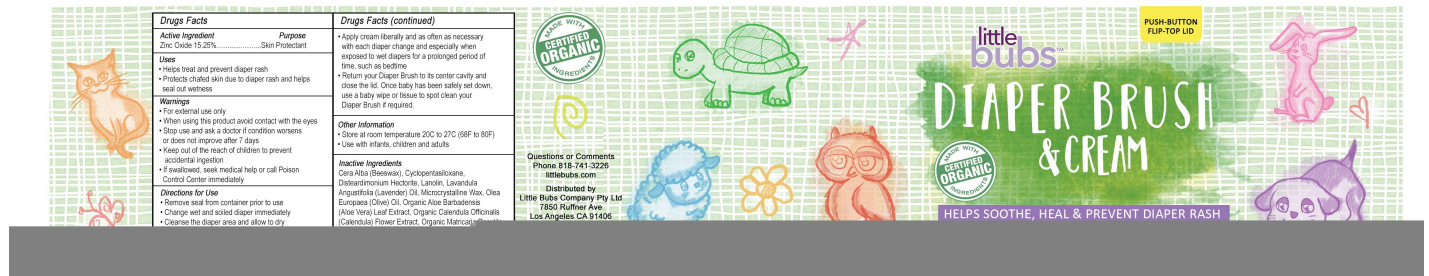
**OTHER INFORMATION**

- STORE AT ROOM TEMPERATURE 20C TO 27C (68F TO 80F)

- USE WITH INFANTS, CHILDREN AND ADULTS

## INACTIVE INGREDIENTS

CERA ALBA (BEESWAX), CYCLOPENTASILOXANE, DISTEARDIMONIUM HECTORITE, LANOLIN, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, MICROCRYSTALLINE WAX, OLEA EUROPAEA (OLIVE) OIL, ORGANIC ALOE BARBADENSIS (ALOE VERA) LEAF EXTRACT, ORGANIC CALENDULA OFFICINALIS (CALENDULA) FLOWER EXTRACT, ORGANIC MATRICARIA RECUTITA (CHAMOMILE) FLOWER EXTRACT, OZOKERITE, PARAFFIN WAX, POLYSORBATE 60, PROPYLENE CARBONATE, SORBITAN SESQUIOLEATE



## LITTLE BUBS DIAPER

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72849-101
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	15.25 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
LANOLIN (UNII: 7EV65EAW6H)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
OLIVE OIL (UNII: 6UYK2WIW1E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CHAMOMILE (UNII: FGL3685T2X)	
CERESIN (UNII: Q1LS2UJO3A)	
PARAFFIN (UNII: I9O0E3H2ZE)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

PROPYLENE CARBONATE (UNII: 8D08K3S51E)

SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72849-101-11	350 g in 1 JAR; Type 0: Not a Combination Product	07/05/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/05/2019	

**Labeler** - LITTLE BUBS COMPANY PTY LTD (890711880)

### Establishment

Name	Address	ID/FEI	Business Operations
Health Specialty		794053863	manufacture(72849-101)

Revised: 7/2019

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