

**BABY WIPE PREMIUM- high quality cotton non-woven fabric cloth**  
**SHINWA INTERNATIONAL CORPORATION**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**BABY WIPE PREMIUM**

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**Active Ingredient(s)**

BENZALKONIUM CHLORIDE 0.1% w/w, Antiseptic

**Purpose**

Antiseptic, BABY WIPE PREMIUM

**Use**

BABY WIPE PREMIUM to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings**

For external use only.

**Do not use**

- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

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**Directions**

- Wipe the skin and let it dry naturally.
- Supervise children under 6 years of age when using this product to avoid swallowing.


**Other information**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

PURIFIED WATER  
PROPYLEN GLYCOL  
DISODIUM COCOAMPHODIACETATE  
2-BROMO-2-NITROPROPANE 1.3-DIOL

**Package Label - Principal Display Panel**

Drug Facts		Drug Facts (continued)
<b>Active ingredients</b> Benzalkonium Chloride 0.1% w/w	<b>Purpose</b> Antiseptic	<b>Keep out of reach of children</b> <ul style="list-style-type: none"> <li>■ If swallowed, get medical help or contact a Poison Control Center right away.</li> <li>■ For children under 6, use only under adult supervision.</li> </ul>
<b>Use(s)</b> <ul style="list-style-type: none"> <li>■ Use for baby: wiping baby while eating, changing diapers or used to wipe sweat.</li> <li>■ Use for family personal hygiene, makeup removal, travel, sports.</li> </ul>	<b>Directions:</b> 	
<b>Warnings</b> <ul style="list-style-type: none"> <li>■ Flammable, keep away from fire or flames</li> <li>■ For external use only</li> </ul>	<b>When using this product</b> <ul style="list-style-type: none"> <li>■ Do not get into eyes</li> <li>■ If contact occurs, rinse eyes thoroughly with water</li> <li>■ Avoid contact with wounds</li> </ul>	<b>Other information</b> <ul style="list-style-type: none"> <li>■ Store below 100°F (41°C)</li> <li>■ May discolor certain fabrics or surfaces</li> </ul>
<b>Stop use and ask a doctor if</b> Irritation and redness develop		<b>Inactive ingredients</b> 2-Bromo-2-Nitropropane-1,3-Diol, Propylene Glycol, Disodium cocamphodisulfate, Purified Water

## BABY WIPE PREMIUM



### BABY WIPE PREMIUM



- ✓ BEST CHOICE
- ✓ HIGH QUALITY
- ✓ 99% ANTIBACTERIAL

### SKINCARE FOR FAMILY

100% NATURAL ESSENCE SUITABLE FOR ALL SKIN TYPES  
ESPECIALLY SENSITIVE BABY SKIN



**DESCRIPTION GOODS:**

- 100% natural essence suitable for all skin types, especially sensitive baby skin
- The product has a mild, soft, absorbent odor that keeps the baby's skin dry and smooth
- With disinfectant properties, anti-diaper rash keeps baby's skin healthy
- Aloe vera extract is a natural moisturizer that keeps baby's skin soft



Products owned by:  
SHINWA INTERNATIONAL CORPORATION

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MADE IN VIETNAM



8 938539 149186

PACK  
50 WIPES



## BABY WIPE PREMIUM

high quality cotton non-woven fabric cloth

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81889-501
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 in 100

### Inactive Ingredients

Ingredient Name	Strength
<b>DISODIUM COCOAMPHODIACETATE</b> (UNII: 18L9G3U51M)	
<b>BRONOPOL</b> (UNII: 6PU1E16C9W)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81889-501-01	50 in 1 BAG; Type 0: Not a Combination Product	05/06/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/06/2021	

**Labeler** - SHINWA INTERNATIONAL CORPORATION (673077340)

### Establishment

Name	Address	ID/FEI	Business Operations
SHINWA INTERNATIONAL CORPORATION		673077340	manufacture(81889-501)

Revised: 5/2021

SHINWA INTERNATIONAL CORPORATION