

**PREMIERPRO FLUSHABLE WIPES WITH DIMETHICONE- dimethicone swab  
HANGZHOU GUOGUANG TOURING COMMODITY CO., 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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**61312-010 PremierPro Flushable Wipes with Dimethicone  
Personal Cleansing Cloths with Dimethicone, 42 count**

***Drug Facts***

***Active Ingredient***

Dimethicone 3.2%

***Purpose***

Skin Protectant

***Uses:***

Helps treat and prevent diaper rash. Protects chafed skin associated with diaper rash and helps protect from wetness. Temporarily protects and helps relieve chapped or cracked skin.

***Warnings:***

**For external use only.**

- Avoid contact with the eyes

**Stop use**

and contact a physician if condition worsens, symptoms last more than 7 days or clear up and occur again within a few days.

**Keep out of reach of children**

If swallowed, get medical help or contact Poison Control Center right away.

**Do not use:**

- On deep or puncture wounds • Animal bites • Serious burns

***Directions:***

Pull back label and remove wipes

- Thoroughly cleanse soiled area, using one wipe at a time
- Use as often as necessary
- Dispose of cloths in a waste receptacle
- Do not flush

**Heating Instructions :**

- Wipes may be used at room temperature but if heating is desired, wipes may be warmed in a wipes

warmer. Wipes should be warmed:

- **in a single warming session** at temperatures **not exceeding** 52°C (125°F) and
- for a **maximum** of 4 days. Discard wipes that have been:
- Exposed to warming temperatures exceeding 52C (125F); or
- Stored longer than 4 days within the warmer; **or**
- Been warmed, allowed to cool, and then re-warmed.

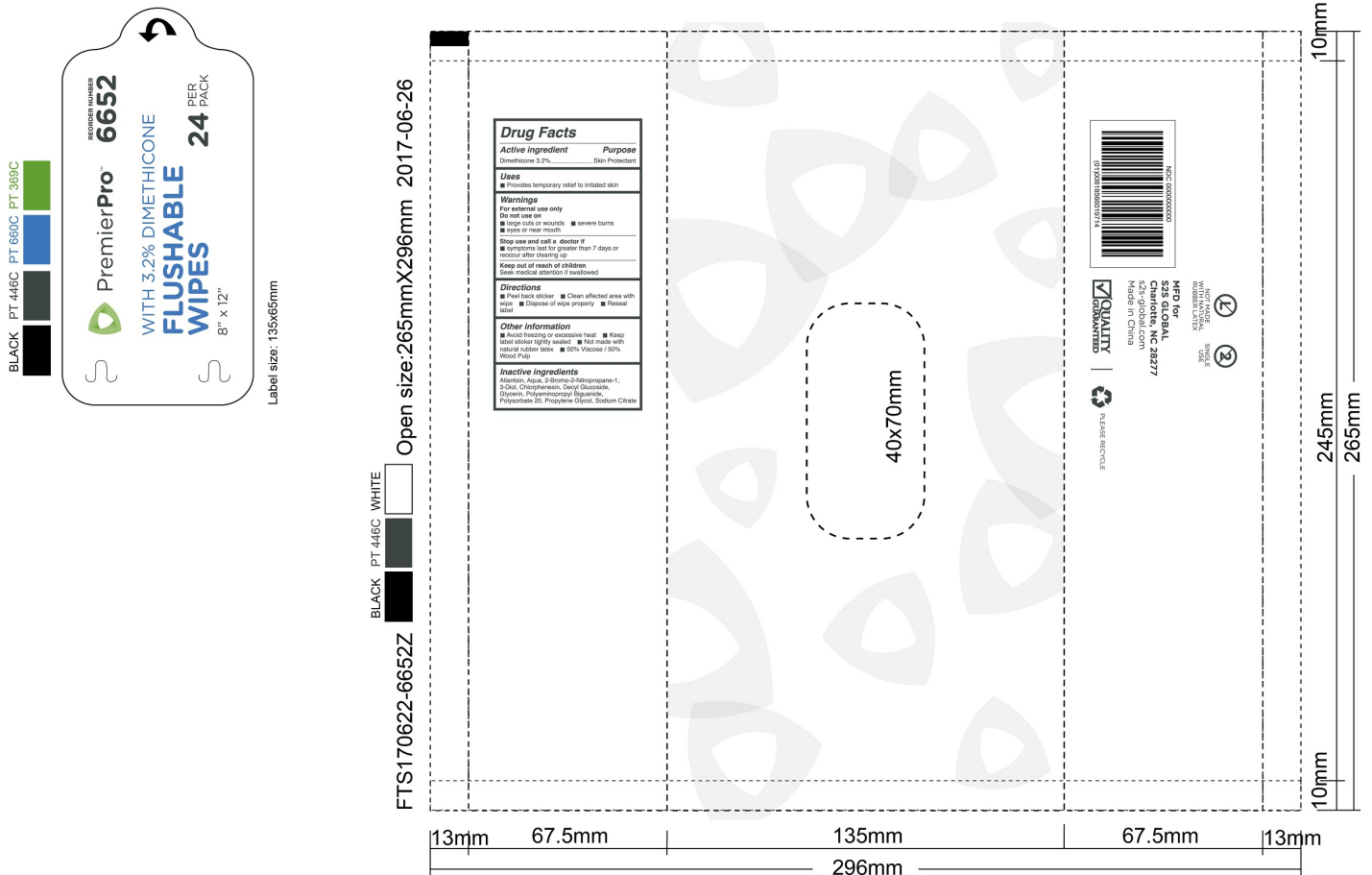
**Other Information:**

- When not in a warmer, store between 15-30°C (59-86°F)

**Inactive Ingredients:**

Allantoin, Aqua, 2-Bromo-2-Nitropropane-1, 3-Diol, Chlorphenesin, Decyl Glucoside, Glycerin, Polyaminopropyl Biguanide, Polysorbate 20, Propylene Glycol, Sodium Citrate

**Package Labeling:**



<b>PREMIERPRO FLUSHABLE WIPES WITH DIMETHICONE</b>			
dimethicone swab			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:6 1312-0 10

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	32 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALLANTOIN (UNII: 344S277G0Z)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61312-010-01	24 in 1 CASE	07/13/2017	
1		216 g in 1 PACKAGE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/13/2017	

**Labeler** - HANGZHOU GUO GUANG TOURING COMMODITY CO., LTD. (526890634)

### Establishment

Name	Address	ID/FEI	Business Operations
HANGZHOU GUO GUANG TOURING COMMODITY CO., LTD.		526890634	manufacture(61312-010)

Revised: 1/2018

HANGZHOU GUO GUANG TOURING COMMODITY CO., LTD.