

EFFERVESCENT HAND SANITIZER- benzalkonium chloride tablet
Enping Jiaxin Daily Necessities 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.

Effervescent Hand Sanitizer

Active Ingredient(s)

Benzalkonium Chloride 8%. Purpose: Antiseptic

Purpose

Antiseptic, Clean&sanitizing hands

Use

Disposable Effervescent Tablets Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- 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

- After dissolution, place enough product on hands to cover all surfaces. Rub hands together until dry.
- 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

Sodium Bicarbonate, Citric Acid, Sodium Sulfate, Cetylpyridinium Chloride, PEG-8, Glycerin, Aloe Barbadensis Leaf Extract

Package Label - Principal Display Panel



EFFERVESCENT HAND SANITIZER

benzalkonium chloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75111-901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	8 in 100

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics					
Color	yellow, red, purple, green, pink, white, blue			Score	score with uneven pieces
Shape	ROUND			Size	20mm
Flavor	APPLE, ORANGE, LEMON, PEACH, MINT, VANILLA, CITRUS, HONEY, PEPPERMINT, LIME, BERRY, FRUIT, STRAWBERRY, RAISIN, TUTTI FRUTTI, MANGO, MENTHOL, BANANA, BLACKBERRY, BUTTERSCOTCH, COCONUT, BLUEBERRY			Imprint Code	No
Contains					
Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:75111-901-01	1 in 1 BAG; Type 0: Not a Combination Product	03/30/2020		
2	NDC:75111-901-02	8 in 1 BAG; Type 0: Not a Combination Product	03/30/2020		
3	NDC:75111-901-03	10 in 1 BAG; Type 0: Not a Combination Product	03/30/2020		
4	NDC:75111-901-04	12 in 1 BAG; Type 0: Not a Combination Product	03/30/2020		
5	NDC:75111-901-05	15 in 1 BAG; Type 0: Not a Combination Product	03/30/2020		
6	NDC:75111-901-06	20 in 1 BAG; Type 0: Not a Combination Product	03/30/2020		
7	NDC:75111-901-07	30 in 1 BAG; Type 0: Not a Combination Product	03/30/2020		
8	NDC:75111-901-08	36 in 1 BAG; Type 0: Not a Combination Product	03/30/2020		
9	NDC:75111-901-09	50 in 1 BAG; Type 0: Not a Combination Product	03/30/2020		
10	NDC:75111-901-10	100 in 1 BAG; Type 0: Not a Combination Product	03/30/2020		
11	NDC:75111-901-11	8 in 1 BOX; Type 0: Not a Combination Product	03/30/2020		
12	NDC:75111-901-12	10 in 1 BOX; Type 0: Not a Combination Product	03/30/2020		
13	NDC:75111-901-13	12 in 1 BOX; Type 0: Not a Combination Product	03/30/2020		
14	NDC:75111-901-14	15 in 1 BOX; Type 0: Not a Combination Product	03/30/2020		
15	NDC:75111-901-15	20 in 1 BOX; Type 0: Not a Combination Product	03/30/2020		
16	NDC:75111-901-16	30 in 1 BOX; Type 0: Not a Combination Product	03/30/2020		
17	NDC:75111-901-17	36 in 1 BOX; Type 0: Not a Combination Product	03/30/2020		
18	NDC:75111-901-18	50 in 1 BOX; Type 0: Not a Combination Product	03/30/2020		
19	NDC:75111-901-19	100 in 1 BOX; Type 0: Not a Combination Product	03/30/2020		
20	NDC:75111-901-20	400 in 1 BOX; Type 0: Not a Combination Product	03/30/2020		
Marketing Information					
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final		part333A	03/30/2020		

Labeler - Enping Jiaxin Daily Necessities Co., Ltd. (403010421)

Establishment				
Name		Address	ID/FEI	Business Operations
Enping Jiaxin Daily Necessities Co., Ltd.			403010421	manufacture(75111-901)

Revised: 2/2021

Enping Jiaxin Daily Necessities Co., Ltd.