

MOUTH FRESH - cetylpyridinium chloride spray
Yuyao Jessie 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.

Antibacterial Wet Wipes

Active Ingredient

Cetylpyridinium Chloride 0.05%

Purpose

Sterilization

Use

sterilization

WARNINGS

For External use only.

Do not use if you are allergic to any of the ingredients.

When using this product Do not get into eyes,if contact occurs ,rinse throughly with water.

Discontinue use if irritation or redness develops if condition persists for more than 72 hours consults a physician.

keep out of reach of children

keep out of reach of children unless under adult supervision .if seallowed ,get medical help or contact a Poison Control Center immediately.

Directions

Open Cap to on position exposing nozzle Pump 1-2 sprays directly into mouth.

Children under 6 months of age:ask a doctor

Inactive ingredients

WATER (Aqua),Alcohol,Glycerin,Sorbitol,Aroma,PEG-40 hydrogenated Castor Oil,Sodium Benzoate,Citric Acid ,Limonene

Drug Facts	Antibacterial Wet Wipes	Drug Fact(Continued)	
Active Ingredient Benzalkonium chloride 0.13%.....Antiseptic		Purpose Antiseptic	
Uses For hand washing to decrease bacteria on skin		Directions For Use Thoroughly wipe hands or face with wipe.Discard in trash receptacle;do not flush.Be sure to reseal label complete to retain moisture.	
Warnings <ul style="list-style-type: none"> ■For external use only ■Do not use if you are allergic to any of the ingredients ■When using this products do not get into eyes.if contact occurs,rinse thoroughly with water ■Discontinus use if irritation or redness develops if condition persists for more than 72 hours consult a physician ■Keep out of reach of children unless under adult supervision.If seallowed, get medical help or contact a Poison Control Center immeddiately. 		Inactive Ingredients Wate,Propylene Glycol,Disodium EDTA,Chloromethylisothiazolinone & Methylisothiazolinone,Potassium Sorbate,Quaternium-15,Aloe Barbadensis Leaf Juice,Dissodium Cocoamphodjacetate,Tocophery Acetate,Polysorbate-20,Citric Acid,Fragrance	
		Made in China	Manufactured by:YuYao Jessie Commodity Co.,Ltd

MOUTH FRESH				
cetylpyridinium chloride spray				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51414-500	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYL PYRIDINIUM - UNII:CUB7JI0JV3)		CETYL PYRIDINIUM CHLORIDE	0.05 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)				
CHLOROMETHYL METHYL ETHER (UNII: 334G5B96VG)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
QUATERNIUM-15 (UNII: E40U03LEM0)				
DISODIUM CO CO AMPHODIACETATE (UNII: 18L9G3U51M)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
CITRIC ACID ACETATE (UNII: DSO12WL7AU)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51414-500-01	2 mL in 1 PACKAGE		
2	NDC:51414-500-02	3 mL in 1 PACKAGE		
3	NDC:51414-500-03	4 mL in 1 PACKAGE		
4	NDC:51414-500-04	5 mL in 1 PACKAGE		
5	NDC:51414-500-05	6 mL in 1 PACKAGE		

6	NDC:51414-500-06	7 mL in 1 PACKAGE		
7	NDC:51414-500-07	8 mL in 1 PACKAGE		
8	NDC:51414-500-08	9 mL in 1 PACKAGE		
9	NDC:51414-500-09	10 mL in 1 PACKAGE		
10	NDC:51414-500-10	15 mL in 1 PACKAGE		
11	NDC:51414-500-11	20 mL in 1 PACKAGE		
12	NDC:51414-500-12	25 mL in 1 PACKAGE		
13	NDC:51414-500-13	30 mL in 1 PACKAGE		
14	NDC:51414-500-14	35 mL in 1 PACKAGE		
15	NDC:51414-500-15	40 mL in 1 PACKAGE		
16	NDC:51414-500-16	45 mL in 1 PACKAGE		
17	NDC:51414-500-17	50 mL in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/12/20 12	

Labeler - Yuyao Jessie Commodity Co.,Ltd. (529892305)

Establishment

Name	Address	ID/FEI	Business Operations
Yuyao Jessie Commodity Co.,Ltd.		529892305	manufacture(51414-500)

Revised: 9/2012

Yuyao Jessie Commodity Co.,Ltd.