PURE FINE MEDIWIPER- benzalkonium chloride liquid
Hyosung SP 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.

Drug Facts

ACTIVE INGREDIENT

Active Ingredients: Benzalkonium Chloride 0.1%

INACTIVE INGREDIENT

Inactive Ingredients:

Water, Glycerin, Sodium benzoate, Polysorbate 20, Disodium EDTA, Phenoxyethanol, Tocopheryl acetate, Citric acid

PURPOSE

Purpose: antiseptic

KEEP OUT OF REACH OF CHILDREN

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

Uses

Uses:

■ instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease
■ instant hand antiseptic to decrease bacteria on the skin

WARNINGS

Warnings

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

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Do not use
• in combination with soap or antibacterial cleansing agents
• the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin. It is not recommended to use this one areas that have been medically treated with a cast or bandage

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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 hypersensitivity symptoms such as erythema, itching and dermatitis happen or skin irritation happens.

Directions

Directions:

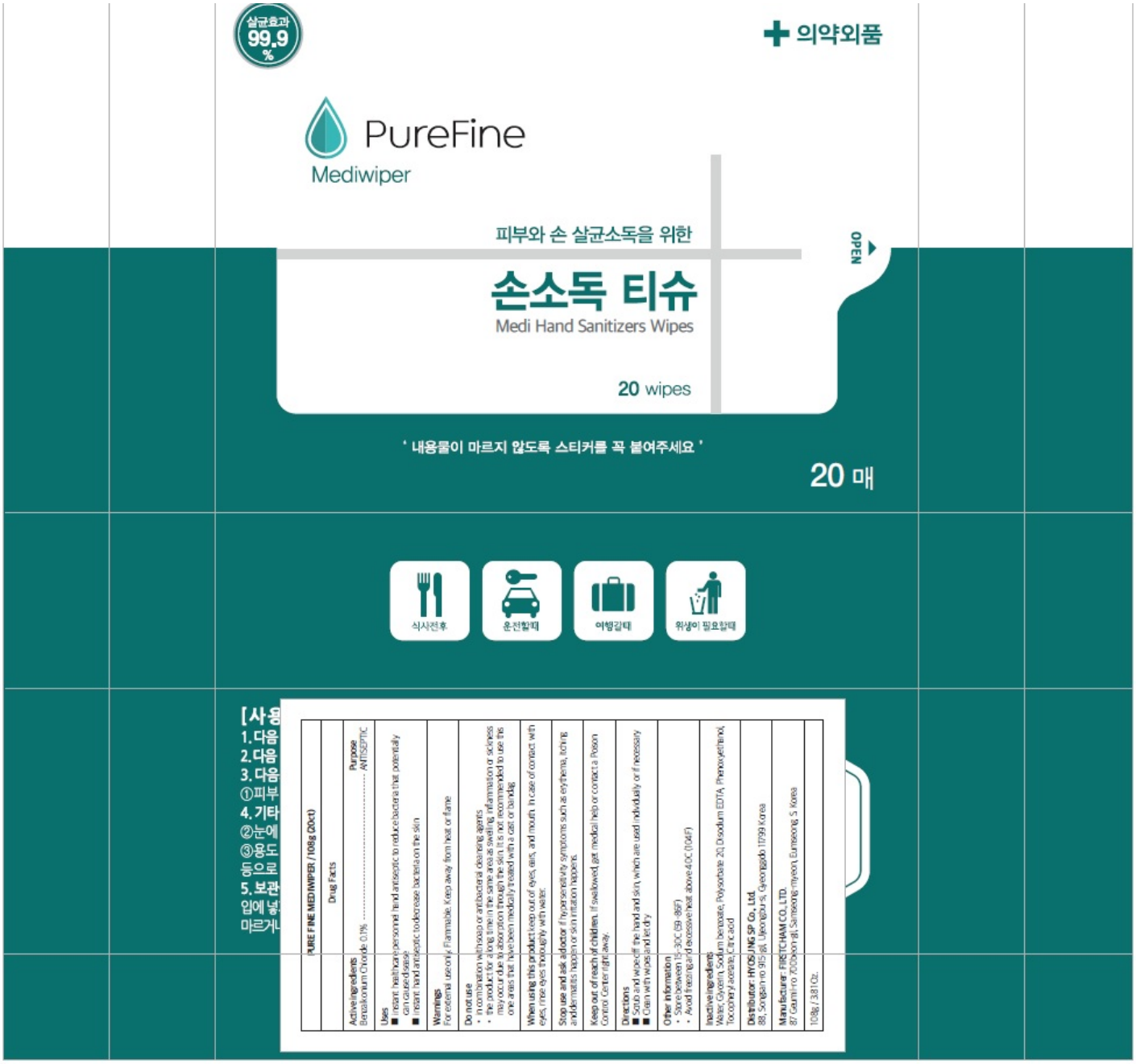
■ Scrub and wipe off the hand and skin, which are used individually or if necessary
■ Clean with wipes and let dry

Other information

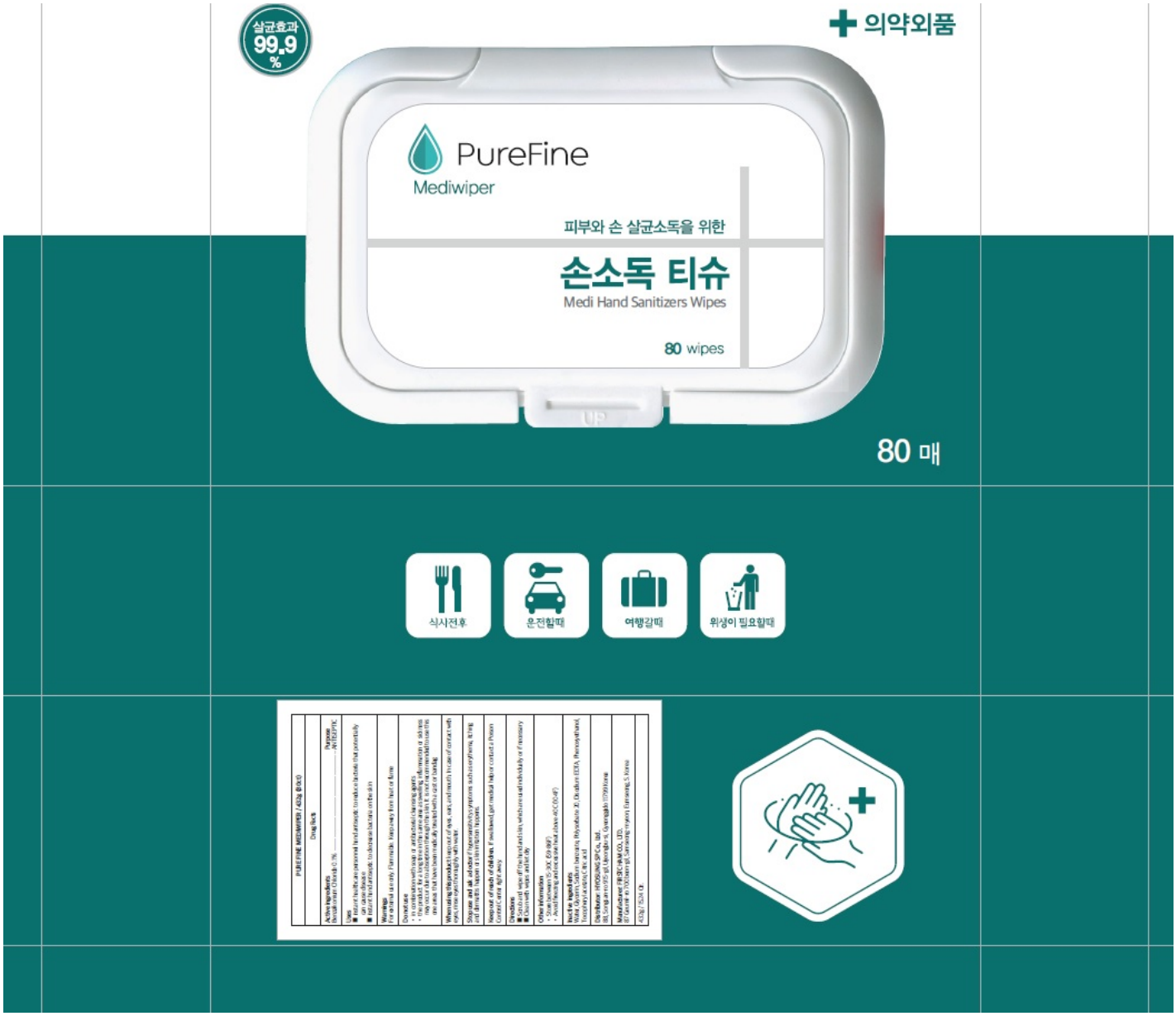
Other information:

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

Package Label - PURE FINE MEDIWIPER 108g, 20ct



Package Label - PURE FINE MEDIWIPER 432g, 80ct



PURE FINE MEDIWIPER

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76522-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**

WATER (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76522-010-01	108 g in 1 CONTAINER; Type 0: Not a Combination Product	04/01/2020	
2	NDC:76522-010-02	432 g in 1 CONTAINER; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/01/2020	

Labeler - Hyosung SP Co.,Ltd (557804880)

Registrant - Hyosung SP Co.,Ltd (557804880)

Establishment

Name	Address	ID/FEI	Business Operations
FIRSTCHAM CO., LTD		689905446	manufacture(76522-010)

Revised: 4/2020 Hyosung SP Co.,Ltd