ANTISEPTIC- benzalkonium chloride liquid
Safetec of America

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.

ANTISEPTIC – Benzalkonium chloride liquid
Safetec of America

Benzalkonium Chloride
Antiseptic towelette

Drug Facts

Active Ingredients

Benzalkonium Chloride 0.13%

Purpose

First Aid Antiseptic

Uses

- Antiseptic cleansing of face, hands and body to decrease bacteria on skin without soap and water

Warnings

For external use only.

Do not use in the eyes. If this happens, rinse thoroughly with water.

Stop use and ask doctor if irritation or redness develop and persists for more than 72 hours

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

Directions

- tear open packet, unfold and use as a washcloth. Allow hands to dry without wiping.

Inactive ingredients

purified water, alcohol

PRINCIPAL DISPLAY PANEL – pouch label

Safetec

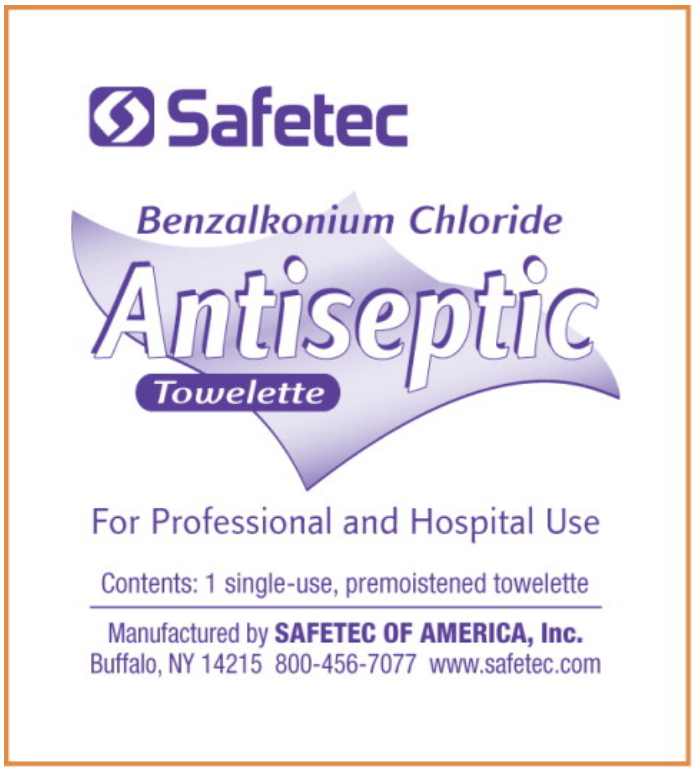
Benzalkonium Chloride
Antiseptic
Towelette

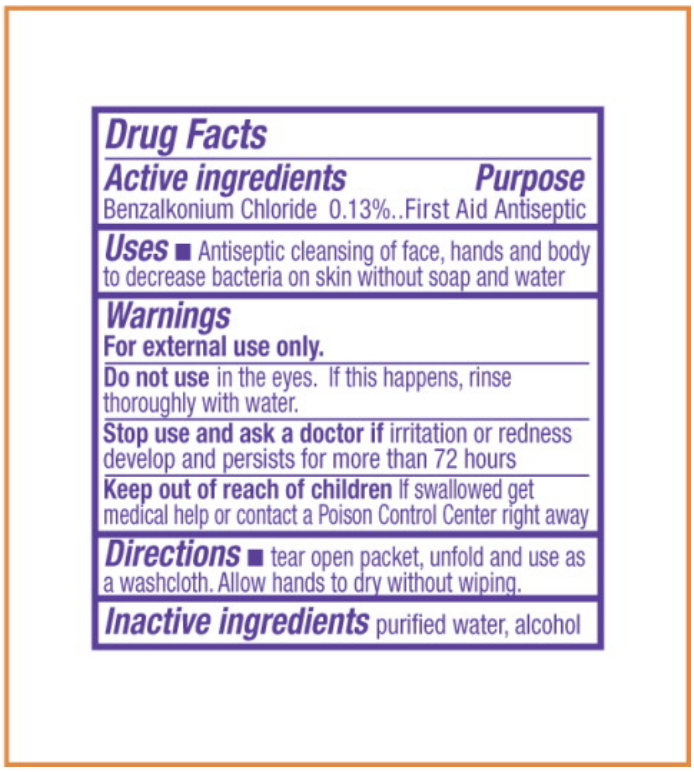
For Professional and Hospital Use

Contents: 1 single-use, premoistened towelette

Manufactured by SAFETEC OF AMERICA, Inc.

Buffalo, NY 14215 800-456-7077 www.safetec.com





PRINCIPAL DISPLAY PANEL – box label

NDC 61010-7110-1

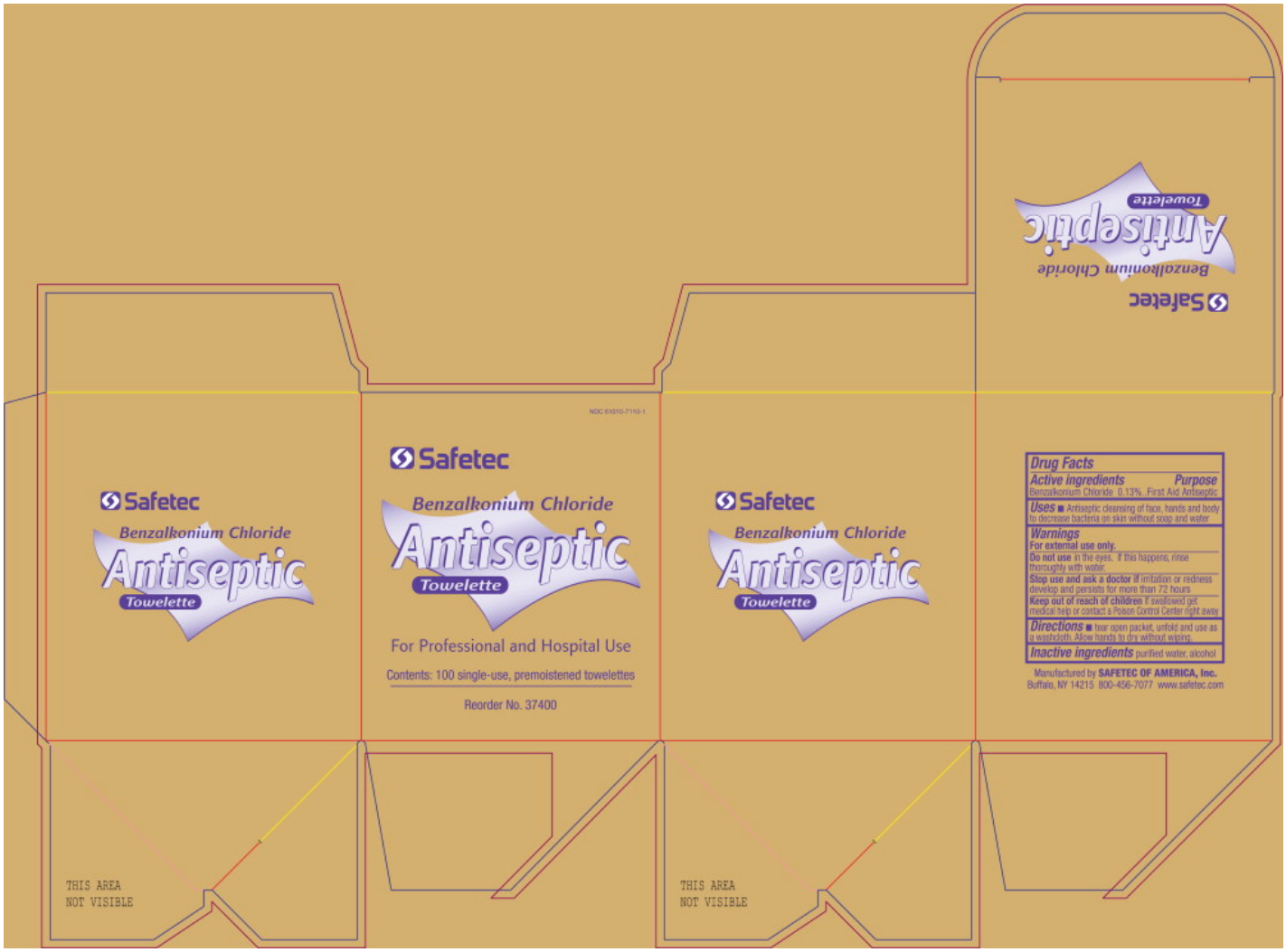
Safetec

Benzalkonium Chloride
Antiseptic
Towelette

For Professional and Hospital Use

Contents: 100 single-use, premoistened towelettes

Reorder No. 37400



ANTISEPTIC

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61010-7110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
benzalkonium chloride (UNII: F5UM2KM3W7) (benzalkonium - UNII:7N6JUD5X6Y)	benzalkonium chloride	1.30 mL in 1 L

Inactive Ingredients	
Ingredient Name	**Strength**
water (UNII: 059QF0KO0R)	
alcohol (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-7110-1	100 in 1 BOX		
1	NDC:61010-7110-0	0.0025 L in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/12/2011	

Labeler - Safetec of America (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE

Revised: 7/2011 Safetec of America