FOAMING INSTANT HAND SANITIZER- benzethonium chloride liquid Pro Source Distributors, Inc.

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.

Foaming Instant Hand Sanitizer 6575 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

benzethonium chloride USP 0.2%

Drug Facts Box OTC-Indications & Usage Section

For hand-washing to decrease bacteria on the skin, only when water is not available

Drug Facts Box OTC-Warnings Section

For external use only

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box-OTC When Using Section

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Drug Facts Box-OTC Stop Use Section

irritation and redness develop

Drug Facts Box-OTC Keep Out Of Reach Of Children Section

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

Drug Facts Box-OTC Dosage & Administration Section

press pump twice to deliver two squirts (about a quarter size) of foaming product onto the palm of your hand

rub hands together until dry

wash hands with soap and water at earliest opportunity

Drug Facts Box-OTC Inactive Ingredient Section

water, glycerine, dimethicone, DMDM hydantoin, iodopropynl butylcarbamate, fragrance

Foaming Instant Hand Sanitizer 6575 Drug Facts and Label



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FOAMING INSTANT HAND SANITIZER

benzethonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72234-575
Route of Administration	TOPICAL		
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHO NIUM CHLO RIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	2 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
DMDM HYDANTO IN (UNII: BYR0 546 TOW)			
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72234-575- 10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	05/29/2018	
2	NDC:72234-575- 18	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/29/2018	
3	NDC:72234-575- 14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/29/2018	
4	NDC:72234-575- 12	1000 mL in 1 BAG; Type 0: Not a Combination Product	05/29/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	05/29/2018		

Labeler - Pro Source Distributors, Inc. (837372085)

Registrant - ABC Compounding Co., Inc. (003284353)

Establishment				
Name	Address	ID/FEI	Business Operations	
ABC Compounding Co., Inc.		003284353	manufacture(72234-575)	

Revised: 1/2020 Pro Source Distributors, Inc.