FOAMAHOL - alcohol liquid Share Corporation

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.

Foamahol 6585 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Ethyl Alcohol 62%

Drug Facts Box OTC-Purpose Section

Antiseptic

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

FLAMMABLE, keep away from fire and flames

For external use only

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 and allow to dry without wiping

Drug Facts Box OTC-Inactive Ingredient Section

water, PEG-10 acrylate, perfluorohexylethyl acrylate copolymer, propylene glycol, fragrance

Foamahol 6585



Foamahol 6585

FOAMAHOL

alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68654-855	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 mL in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PEG-10 ACRYLATE/PERFLUOROHEXYLETHYL ACRYLATE COPOLYMER (UNII: D76Z87928N)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68654-855- 17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/11/2019	
2	NDC:68654-855- 14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/11/2019	
3	NDC:68654-855- 18	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/11/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	07/11/2019		

Labeler - Share Corporation (053687356)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
ABC Compounding Co., Inc.		003284353	manufacture(68654-855)	

Revised: 7/2019 Share Corporation