

RECENS FOAM- alcohol liquid
Certus Medical, 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.

Recens Foam 6792 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

ffor 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

apply to hands and rub lightly until dry without wiping or rinsing

Drug Facts Box OTC-Inactive Ingredient Section

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

Recens Foam 6792

Recens Foam

Foam waterless antiseptic hand rinse with lotion

DANGER: FLAMMABLE

KEEP OUT OF REACH OF CHILDREN

KEEP AWAY FROM FIRE OR FLAME. FOR EXTERNAL USE ONLY.

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 62%.....	Antiseptic

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

Warnings

Flammable, keep away from fire and flames
For external use only

When using this product

- do not get into eyes
- if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop

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

Directions ■ 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

Inactive Ingredients water, PEG-10 Acrylate, Perfluorohexylethyl Acrylate Copolymer; Perfluorohexylethyl Alcohol, Propylene Glycol

6792P6LM.052219

Manufactured for Certus Medical, Inc.
P. O. Box 16247
Atlanta, GA 30321-0247
www.certusmedical.com

1000 ML (33.8 FL. OZ.)

Reorder No.: 6792P6LM



7 11808 21079 8

RECENS FOAM

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75990-6792
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: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-10 ACRYLATE/PERFLUOROHXYLETHYL ACRYLATE COPOLYMER (UNII: D76Z87928N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75990-6792-7	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2019	
2	NDC:75990-6792-1	1000 mL in 1 BAG; Type 0: Not a Combination Product	07/08/2019	
3	NDC:75990-6792-3	800 mL in 1 BAG; Type 0: Not a Combination Product	07/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/08/2019	

Labeler - Certus Medical, Inc. (966433653)

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(75990-6792)