

PROANDRE- alcohol denat aerosol, foam

Proandre SL

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.

Antibacterial Handsanitizer Foam

Active Ingredient

Active Ingredient Purpose

Alcohol Denat 68%..... Antibacterial

Uses

Uses

* Hand Sanitizer to help reduce bacteria that potentially may cause disease

Warnings

For external use only

Flammable. Keep away from fire or flame

When using this product

* Avoid contact with face, eyes and broken skin.

If eye contact occurs, flush thoroughly with water and seek medical advice.

Stop use and ask a doctor if

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* Irritation and redness develops

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.

Directions

Directions

* Pump liquid into dry hands, wet thoroughly and rub into skin until dry.

* Children under 6 years of age should be supervised by an adult when using this product.

Inactive Ingredients

Water, Cocamidopropyl betaine

Questions?

Questions?

1(305) 961 1156

Uses

Hand sanitizer to help reduce bacteria on hands. Avoid contact with broken skin

Antibacterial Hand Sanitizer Foam

Antibacterial Hand Sanitizer Foam

Fragrance Free



ANTIBACTERIAL Hand Sanitizer FRAGRANCE FREE FOAM

Drug Facts

Active Ingredient	Purpose
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Drug Facts (continued)

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Inactive Ingredients Water.

Questions? +1 (305) 961 1156

800ml (27.05 fl.oz.)



*Tested on latex and nitrile gloves



MADE IN SPAIN BY PROANDRE SL

C/ Condestable de Portugal, 43-45-3º 08402 Granollers (Barcelona) - Spain

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alcohol denat aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70028-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	10 mg in 1 mL
WATER (UNII: 059QF0KO0R)	50 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70028-003-11	800 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/20/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/20/2017	

Labeler - Proandre SL (463207675)

Registrant - Proandre SL (463207675)

Establishment

Name	Address	ID/FEI	Business Operations
Pro andre SL		463207675	manufacture(70028-003)

Revised: 6/2017

Proandre SL