

PROANDRE- benzalkonium chloride liquid

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.

Active Ingredient Purpose

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Benzalkonium Chloride 0.1%.....Antibacterial

Uses

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* Helps to eliminate bacteria on hands. Avoid contact with broken skin

Directions

- * Wash for 15-20 seconds
- * Rinse and dry hands thoroughly.
- * Children under 6 years of age should be supervised by an adult when using this product

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WARNINGS

For External Use only

When using this product:

* Avoid contact with face, eyes and broken skin if eyes contact occurs, flush thoroughly with water and seek medical advice.

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Stop use and ask doctor if

* Irritation and redness develops.

Keep Out of reach of children

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

Questions?.

+ 1 (305) 961 1156

Dossage and Administration

- * Wash for 15-20 seconds
- * Rinse and dry hands thoroughly.
- * Children under 6 years of age should be supervised by an adult when using this product

Inactive ingredients

Water, Cocamidopropylbetaine, sodium chloride, potassium sorbate, sodium benzoate, citric acid, FD&C Yellow 5, FD&C Red 40.

ANTIBACTERIAL ANTIBACT SOAP LIQUID

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Fragrance free

10,5x10,5 cm



ANTIBACTERIAL

Antibact Soap

FRAGRANCE FREE LIQUID

<p>Drug Facts</p> <p>Active Ingredient Purpose Benzalkonium Chloride, 0.1%.....Antibacterial</p> <p>Uses ❖ Helps to eliminate bacteria on hands. Avoid contact with broken skin.</p> <p>Warnings For external use only</p> <p>When using this product ❖ Avoid contact with face, eyes and broken skin, if eye contact occurs, flush thoroughly with water and seek medical advice.</p> <p>Stop use and ask a doctor if ❖ Irritation and redness develops</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>Drug Facts (continued)</p> <p>Directions ❖ Wash for 15-20 seconds. ❖ Rinse and dry hands thoroughly. ❖ Children under 6 years of age should be supervised by an adult when using this product.</p> <p>Inactive Ingredients Water, Cocamidopropylbetaine, Sodium Chloride, Potassium Sorbate, Sodium Benzoate, Citric Acid, FD&C Yellow 5, FD&C Red No. 40.</p> <p>Questions? +1 (305) 961 1156</p> <p style="font-size: 24pt; font-weight: bold;">800ml (27.05 fl.oz.)</p> <p>Install with label toward wall. Instalar con etiqueta hacia la pared.</p> <div style="text-align: center;">  <p>*Tested on latex and nitrile gloves</p> </div>
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MADE IN SPAIN BY
PROANDRE SL
 C/ Condestable de Portugal, 43-45-3º
 08402 Granollers (Barcelona) - Spain
www.proandre.com
info@proandre.com

5x5 cm

ANTIBACTERIAL

Antibact Soap

FRAGRANCE FREE LIQUID

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800ml (27.05 fl.oz.)

PROANDRE

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70028-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	80.079 mg in 1 mL
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	18.1 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.9 mg in 1 mL

POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.3 mg in 1 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.3 mg in 1 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	0.02 mg in 1 mL
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	0.0005 mg in 1 mL
FD&C RED NO. 40 (UNII: WZB9127XOA)	0.0005 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70028-002-01	800 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/26/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/20/2015	

Labeler - PRO ANDRE, SL (463207675)

Registrant - PRO ANDRE, SL (463207675)

Establishment

Name	Address	ID/FEI	Business Operations
PROANDRE, SL		463207675	manufacture(70028-002)

Revised: 11/2016

PROANDRE, SL