

ICS3 PINK HEALTHCARE ANTISEPTIC HAND- benzalkonium chloride liquid

Inopak, Ltd

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.

Inopak - ICS3Pink - 162

Drug Facts

Active Ingredient

Benzalkonium chloride 0.13% (w/w)

Purpose

Antiseptic

Keep out of reach of children.

- Keep out of reach of children.

Uses

For hand washing to decrease bacteria on the skin after changing diapers, after assisting ill persons or before contact with a person under medical care or treatment. Recommended for repeated use.

Warnings

- For external use only. Keep out of eyes, ears or mouth.
- Discontinue use if irritation occurs.

Directions

- Dispense a golf ball size amount of foam onto dry hands and rub vigorously for 15 seconds
- Rinse with water and towel dry.

Inactive Ingredients

Cetrimonium chloride, chlorhexidine gluconate, cocamidopropyl PG-dimonium chloride phosphate, D & C Red #33, decyl glucoside, ethyl alcohol, phenoxyethanol, polyquaternium 10, polyquarternium 11, water.

ICS3 Pink label

BIO-5077Q-FL 1000

34 FL OZ

Rev. 1.02

iCS3®

(1000 mL)

INFECTION CONTROL SYSTEM 3

Bio-5077Q-FL

ANTISEPTIC HAND WASH

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888-497-7375

biocentris

info@biocentris.com

PHARMACEUTICALS

www.biocentris.com

BIO-5077Q-FL1000
Rev. 1.2



34 FLOZ
(1000 mL)
Bio-5077Q-FL

INFECTION CONTROL SYSTEM 3

ANTISEPTIC HAND WASH

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888-497-4375
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ICS3 Pink Case

iCS3®

INFECTION CONTROL SYSTEM 3

- O 6 / 1000 mL Pouches
- BIO-5077Q-FL1000
- 040232 65000 0

ANTISEPTIC FOAM

HAND WASH

- O 6/1000 mL Cartridges
- BIO-5077Q-OS1000
- 040232 65001 7

- O 12 / 18 oz Bottles
- 1.0

- O 24 / 50 mL Bottles

BIO-5076-CASE Rev.

BIO-5077Q-18
4375
040232 65002 4

BIO-5077Q-50
040232 65003 1

Call: 888-497-
info@biocentris.com

www.biocentris.com

Biocentris

PHARMACEUTICALS

ICS3[®] ANTISEPTIC FOAM HAND WASH

INFECTION CONTROL SYSTEM 3

○ **6 / 1000 mL Pouches**
BIO-5077Q-FL1000



○ **6/1000 mL Cartridges**
BIO-5077Q-OS1000



BIO-5077Q-CASE Rev. 1.0

○ **12 / 18 oz Bottles**
BIO-5077Q-18



○ **24 / 50 mL Bottles**
BIO-5077Q-50



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PHARMACEUTICALS

ICS3 PINK HEALTHCARE ANTISEPTIC HAND

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58575-162
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	130 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
ALCOHOL (UNII: 3K9958V90M)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
POLYQUATERNIUM-10 (30000 MPA.S AT 2%) (UNII: C7RDC8Y4JS)	
POLYQUATERNIUM-11 (1000000 MW) (UNII: 0B44BS5IJS)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58575-162-02	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/01/2014	
2	NDC:58575-162-18	532 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/01/2014	
3	NDC:58575-162-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2014	
4	NDC:58575-162-10	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	11/01/2014	
5	NDC:58575-162-11	1000 mL in 1 POUCH; Type 0: Not a Combination Product	11/01/2014	
6	NDC:58575-162-12	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	11/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/01/2014	

Labeler - Inopak, Ltd (194718243)

Registrant - Inopak, Ltd (194718243)

Establishment

Name	Address	ID/FEI	Business Operations
Inopak, Ltd		194718243	manufacture(58575-162)