

ASSURED- benzalkonium chloride swab
INDELPA, S.A. DE C.V.

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.

Benzalkonium Chloride 0.125%

Antibacterial

USE

Decreases bacteria on skin.

For external use only

If you are allergic to any of the ingredients

Do not get into eyes.

If contact occurs, rinse thoroughly with water.

If irritation or rash develops and continues for more than 72 hours

If irritation or rash develops and continues for more than 72 hours

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

-
- Thoroughly wipe hands and face as desired.
 - Allow to dry without wiping.
 - Discard wipe in trash receptacle after use.
 - Do not flush.
-

To dispense wipe: Peel back front label slowly. Remove wipes.

To reseal pouch: Firmly run thumb over the label.

Store at room temperature. Cold weather may cloud this product. It's antiseptic properties are not affected.

Water, Propylene Glycol, Polysorbate 20, Sodium Cocoamphoacetate, Fragrance, Citric Acid, Vitamin E, Methylchloroisothiazolinone, Aloe Extract, Tetrasodium EDTA.

Dosage: Swab

Administration: Topical

Assured™ Antibacterial Wet Wipes kills germs and bacteria, cleans and freshens your skin and gently wipes away perspiration and odor.

With moisturizing formula containing Aloe Vera and Vitamin E, **Assured™ Antibacterial Wet Wipes** are soft and gentle, and helping to nourish your skin as you freshen up.

This travel pack is convenient to take along for use anytime or anywhere.

ASSURED
Antibacterial
Wet Wipes
Hand & face moisturizing towelettes

For hands and face
Ideal for traveling
Moisturizing
Thick and soft cloths
Fresh scent



40 Pre-moistened Wipes

6.692 in. X 6.299 in. (17.0 cm X 16.0 cm)

2.0 cm

5.0 cm

PRESIONE AQUÍ
PUSH TO OPEN

Drug Facts	
Active ingredient Benzalkonium chloride 0.125%	Purpose Antiseptic
Use Use to decrease bacteria on skin.	
Warnings For external use only. Do not use: - over large areas of the body - if you are allergic to any of the ingredients. When using this product avoid contact with eyes.	
Directions Wipe skin and wash a surface if irritation or rash develops and continues for more than 72 hours. Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.	
Directions For adults and children of 2 years and over: - children under 2 years ask a doctor before use - allow to dry without wiping	
Inactive ingredient Benzalkonium Chloride, Propylene Glycol, Polyethylene Glycol, Sodium Cocoyl Sulfonate, Sodium Lauryl Sulfate, Sodium Myristate, Sodium Stearate, Sodium Sulfate, Sodium Hydroxide, Water, Fragrance, Aloe Vera Extract, Tetrasodium EDTA, Citric Acid, D-alpha-Tocopheryl Acetate.	

ASSURED
Antibacterial Wet Wipes
Hand & face moisturizing towelettes

10 count **Travel Pack**

5.51 in x 7.87 in (14 cm x 20.0 cm)

Vitamin E and Aloe

Antibacterial Moist Wipes

- Convenient
- Easy to use & carry anywhere!
- Clean-up
- Use to wash up quickly when soap and water are not available.
- Moisturize
- Contains soothing Aloe to help moisturize your skin and leave it feeling soft and smooth.

For hands and face • Thick and soft cloths
Ideal for traveling • Fresh scent
Moisturizing • Kills germs

Directions for use:
- 1. Remove one wipe from the pack and use on affected area.
- 2. Rub the wipe over the skin to be treated.
- 3. Discard the used wipe in a wastebasket.
- 4. Do not use if the seal is broken or the wipe is dry.

Warnings:
- Keep out of reach of children, especially if they will crawl and play with the wipe.
- Do not use on large areas of the body.
- Do not use if you are allergic to any of the ingredients.
- Do not use if the seal is broken or the wipe is dry.

Directions:
- 1. Remove one wipe from the pack and use on affected area.
- 2. Rub the wipe over the skin to be treated.
- 3. Discard the used wipe in a wastebasket.
- 4. Do not use if the seal is broken or the wipe is dry.

Ingredients:
Water, Propylene Glycol, Polyethylene Glycol, Sodium Cocoyl Sulfonate, Sodium Lauryl Sulfate, Sodium Myristate, Sodium Stearate, Sodium Sulfate, Sodium Hydroxide, Vitamin E, Aloe Vera Extract, Tetrasodium EDTA, Citric Acid, D-alpha-Tocopheryl Acetate.

Net Weight: 10.00 g (0.35 oz)

Net Content: 10.00 g (0.35 oz)

2121-800002

MADE IN CHINA

© 2012
CREATED BY
ALLIANTO PHARMACEUTICAL, INC.
CHICAGO, IL 60631

Antibacterial Travel Wipes

- **Convenient**
Easy to use & carry anywhere!
- **Clean-up**
Use to wash up quickly when soap and water are not available.
- **Moisturize**
Contains soothing Aloe to help moisturize your skin and leave it feeling soft and smooth.

2120-800002



187423
DISTRIBUTED BY
GREENBRIER INTERNATIONAL, INC.
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320
MADE IN MEXICO

ASSURED

Antibacterial Travel Wipes

Hand & face moisturizing towelettes

Vitamin E
and Aloe

ASSURED

Vitamin E
and Aloe

Antibacterial Travel Wipes

Hand & face moisturizing towelettes

- For hands and face
- Ideal for traveling
- Moisturizing
- Thick and soft cloths
- Fresh scent
- Kills germs



30
Total Wipes!

2 Travel Packs

Two 15 count packs
5.11 in x 7.87 in (13.0 cm x 20.0 cm)

Drug Facts

Active ingredient.....Purpose
Benzalkonium Chloride 0.125%.....Antibacterial

Use
For hand washing to decrease bacteria on the skin. May be used on face, arms and legs.

Warnings
For external use only
Do not use if you are allergic to any of the ingredients

When using this product do not get into eyes. If contact occurs, rinse thoroughly with water.
Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours.

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

Directions
• Thoroughly wipe hands and face as desired.
• Allow to dry without wiping.
• Discard wipe in trash receptacle after use. Do not flush.

Other information
Store at room temperature. Cold weather may cloud this product. Its antiseptic properties are not affected.

Inactive ingredients
Water, Propylene Glycol, Polysorbate 20, Sodium Cocamidopropylsulfate, Fragrance, Methylchlorisothiazolinone, Aloe Extract, Tetrasodium EDTA, Citric Acid, Vitamin E.

Drug Facts

Active Ingredient
Benzalkonium chloride 0.125% **Purpose**
Antibacterial

Use decreases bacteria on skin

Warnings

For external use only.
Do not use
- over large areas of the body
- if you are allergic to any of the ingredients

When using this product avoid contact with eyes
if contact occurs, flush thoroughly with water. ▶

Drug Facts (continued)

Stop use and ask a doctor if irritation or rash develops and
continues for more than 72 hours

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

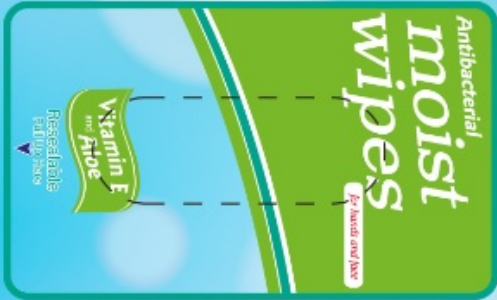
Directions

- for adults and children of 2 years and over
- children under 2 years ask a doctor before use
- allow to dry without wiping

Inactive ingredient

Distilled Water, Triethylene Glycol, Polyethylene 20, Sodium
Dodecylphosphate, Methylchlorohydrate / Methyl salicylate, Fragrance,
Aloe Vera Extract, Tetrasodium EDTA, Citric Acid, D-alpha Tocopheryl Acetate

*Kills germs • Moisturizing formula
Fresh scent • Convenient and portable*



20 Pre-moistened Wipes

5.875 in. X 7.875 in. (15 cm X 20 cm)

Convenient!

Easy to use &
carry anytime!

Clean-up

Use to wash up quickly
when soap and water are not
available.

Moisturize

Soothes & softens dry skin.
Antibacterial Moist Wipes
contain soothing Aloe to help
moisturize your skin and
leave it feeling soft
& smooth. Our Moist Wipes
are thick and strong to help
even the roughest skin.



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GREEN SCIENCE
CORPORATION, INC.
100 WEST HANCOCK ROAD, SUITE 200
WALTON, MA 01885



Travel Pack



40
30 count

ALCOHOL & PARABEN FREE!

5.70 in x 7.48 in (14.5 cm x 19 cm)

Assured™ Antibacterial Wet Wipes kills germs and bacteria, cleans and freshens your skin and gently wipes away perspiration and odor.

With a moisturizing formula containing Aloe Vera and Vitamin E, **Assured™ Antibacterial Wet Wipes** are soft and gentle, and helping to nourish your skin as you freshen up.

This travel pack is convenient to take along for use anytime or anywhere.

Sports

Car

Traveling

Camping

Picnics

Fishing

Boating

Office

Shopping

To dispense wipe: Peel back front label slowly. Remove wipes.

To reseal pouch: Firmly run thumb over the label.

Antibacterial Wet Wipes

Assured™ Antibacterial Wet Wipes are perfect for quick clean-ups when soap and water are not available. Use anytime, anywhere.

Drug Facts	
Active ingredient	Purpose
Benzalkonium Chloride 0.125%	Antibacterial
Use decreases bacteria on skin.	
Warnings	
For external use only	
Do not use if you are allergic to any of the ingredients.	
When using this product do not get into eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Thoroughly wipe hands and face as desired. • Allow to dry without wiping. • Discard wipe in trash receptacle after use. Do not flush. 	
Inactive ingredients	
Water, Propylene Glycol, Polysorbate 20, Sodium Caprylate, Fragrance, Citric Acid, Vitamin E, Methylchlorothiazolone, Aloe Extract, Tetrasodium EDTA.	



39277 35466 2

187431
DISTRIBUTED BY
GREENERBRIER INTERNATIONAL, INC.
580 VOLVO PARKWAY, CHESAPEAKE, VA 23320
MADE IN MEXICO

ASSURED

benzalkonium chloride swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70697-800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.125 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	98.54 mg in 100 mg
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.05 mg in 100 mg
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.3 mg in 100 mg
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPIEW8)	0.01 mg in 100 mg
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.5 mg in 100 mg

SODIUM COCOAMPHOACETATE (UNII: W7Q5E87674)	0.2 mg in 100 mg
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	0.1 mg in 100 mg
EDETATE SODIUM (UNII: MP1J8420LU)	0.03 mg in 100 mg
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.018 mg in 100 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70697-800-03	3 in 1 BAG	06/10/2016	
1		10 in 1 PACKAGE		
1		3 mg in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:70697-800-04	40 in 1 PACKAGE	06/10/2016	
2		0.375 mg in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70697-800-05	20 in 1 PACKAGE	06/10/2016	
3		0.375 mg in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:70697-800-06	2 in 1 PACKAGE	06/10/2016	
4		15 in 1 PACKAGE		
4		2 mg in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:70697-800-07	12 in 1 CASE	06/10/2016	
5		103.2 mg in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/10/2016	

Labeler - INDELPA, S.A. DE C.V. (811072487)

Registrant - INDELPA, S.A. DE C.V. (811072487)

Establishment

Name	Address	ID/FEI	Business Operations
INDELPA, S.A. DE C.V.		811072487	manufacture(70697-800) , analysis(70697-800) , pack(70697-800) , label(70697-800)

Revised: 5/2020

INDELPA, S.A. DE C.V.