BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES VANILLA SUGAR WINTER BERRY PEPPERMINT- benzalkonium chloride ENCHANTE ACCESSORIES 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.

50563-359/360/361/362 G0XABW03

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES Vanilla Sugar

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES Vanilla Sugar

Active Ingredient

Benzalkonium Chloride 0.1%

Purpose

Antibacterial

Use

■ To decrease bacteria on hands

WARNINGS

For external use only

When using this product avoid contact with eyes. In case of contact with eyes, rinse thoroughly with water

Stop use and ask a doctor if irritation or rash occurs. This may be signs of a serious condition

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222

Directions

For adults and children two years and over

Peel over reusable label and remove a wipe from the packet.

Wet hands thoroughly and air dry.

Place used wipes into waste basket. Do not flush.

Inactive ingredients

Aloe Barbadensis Leaf Extract, Ethylhexylglycerin, Fragrance, Glycerin, Phenoxyethanol, Propylene Glycol, Water

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES Winter Berry

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Active Ingredient

Benzalkonium Chloride 0.1%

Purpose:

Antibacterial

Uses:

■ To decrease bacteria on hands

Warnings

For external use only

When using this product avoid contact with eyes. In case of contact with eyes, rinse thoroughly with water

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Directions

For adults and children two years and over

Peel over reusable label and remove a wipe from the packet.

Wet hands thoroughly and air dry.

Place used wipes into waste basket. Do not flush.

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Ethylhexylglycerin, Fragrance, Glycerin, Phenoxyethanol, Propylene Glycol, Water

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES Peppermint

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES Peppermint

Active Ingredient

Benzalkonium Chloride 0.1%

Purpose

Antibacterial

Uses

■ To decrease bacteria on hands

Warnings

For external use only

When using this product avoid contact with eyes. In case of contact with eyes, rinse thoroughly with water

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Directions

For adults and children two years and over

Peel over reusable label and remove a wipe from the packet.

Wet hands thoroughly and air dry.

Place used wipes into waste basket. Do not flush.

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Ethylhexylglycerin, Fragrance, Glycerin, Phenoxyethanol, Propylene Glycol, Water







BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES VANILLA SUGAR WINTER BERRY PEPPERMINT

benzalkonium chloride kit

P	roduct Information			
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:50563-362

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-362-01	1 in 1 KIT	10/20/2020	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	20
Part 2	1 PACKET	20

	Part 3		20
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Part 1 of 3

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES VANILLA SUGAR

benzalkonium chloride solution

Product Information Item Code (Source) NDC:50563-359

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	4.5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		

	Pac	kaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 N	DC:50563-359-01	20 in 1 PACKET; Type 1: Convenience Kit of Co-Package		

Marketing Inform	mation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/20/2020	

Part 2 of 3

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES WINTER BERRY

benzalkonium chloride solution

Product Information	
Item Code (Source)	NDC:50563-360
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	4.5 mg

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				

	Packa	nging			
ı	# It	tem Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:	:50563-360-01	20 in 1 PACKET; Type 1: Convenience Kit of Co-Package		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	10/20/2020		

Part 3 of 3

BODY PRESCRIPTIONS ANTIBACTERIAL HAND WIPES PEPPERMINT

benzalkonium chloride solution

Product Information			
Item Code (Source)	NDC:50563-361		
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	4.5 mg		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
PHENO XYETHANOL (UNII: HIE492ZZ3T)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			

ı	Pac	kaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 ND	C:50563-361-01	20 in 1 PACKET; Type 1: Convenience Kit of Co-Package		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	10/20/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	10/20/2020		

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment				
Name	Address	ID/FEI	Business Operations	
Zhejiang Ruolin Hygienic Products Co., Ltd.		415426870	manufacture(50563-362)	

Revised: 10/2020 ENCHANTE ACCESSORIES INC.