

**GRACIE SQUARE HOSPITAL AMENITY- sodium monofluorophosphate
ASP Global, LLC**

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.

Gracie Square Hospital Amenity Kit

Colgate® Anticavity Toothpaste

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (0.15%)w/v fluoride ion)

Purpose

Anticavity

Use

helps protect against cavities

Warnings

Keep out of the reach of children under 6 years of age.

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 2 years of age and older	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
children under 2 years	ask a dentist or physician

Inactive ingredients

dicalcium phosphate dihydrate, aqua(water), sorbitol, sodium lauryl sulfate, aroma(flavour), cellulose gum, tetrasodium pyrophosphate, sodium saccharin, limonene

Questions or comments?

Call toll-free **1-800-468-6502**

Manufactured by:

COLGATE-PALMOLIVE (THAILAND) Limited, Chonburi 20000, Thailand.

PRINCIPAL DISPLAY PANEL - 10 g Tube Label

Colgate®
Anticavity Toothpaste

Cavity
Protection

NET WT 10g

Manufactured by:

COLGATE-PALMOLIVE (THAILAND) Limited, Chonburi 20000, Thailand.

P1505037



NET WT 10g



Drug Facts See information sheet before using.

Active Ingredient	Purpose
Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)	Anticavity

Use helps protect against cavities

Drug Facts		Drug Facts (continued)	
Active ingredient Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)	Purpose Anticavity	Directions adults and children 2 years of age and older	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
Use helps protect against cavities		children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
Warnings Keep out of the reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.		children under 2 years	ask a dentist or physician
		Inactive ingredients	dicalcium phosphate dihydrate, aqua(water), sorbitol, sodium lauryl sulfate, aroma(flavour), cellulose gum, tetrasodium pyrophosphate, sodium saccharin, limonene
		Questions or comments? Call toll-free 1-800-488-8502	

PRINCIPAL DISPLAY PANEL - Kit Label

GRACIE
SQUARE
HOSPITAL

Item #: GSHAMEN01

Description: Amenity Kit

PO #:

Lot #: XMMDDFC

Exp: YYYY-MM-DD

Qty: 20 KIT/CS

Carton #: X of XX

Net Wt.: XX KG

Gross Wt.: XX KG

Cubic Dimensions: NN x NN x NN CM

Assembled in China

Components Made in China:

- Shampoo/Conditioner
- Body Wash
- Body Lotion
- Alcohol-Free Mouthwash
- Hair Brush
- Toothbrush
- Ear Plugs
- Lip Balm
- Kit Case

Component Made in Thailand:

- Toothpaste

GRACIE
SQUARE
HOSPITAL

We are pleased to
present this welcome kit
for your comfort and
convenience during your
stay.

Thank you for choosing
Gracie Square Hospital
for your healthcare!

Contents/Origins:

2.0 fl. oz. Shampoo/Conditioner
2.0 fl. oz. Body Wash
2.0 fl. oz. Body Lotion
2.2 fl. oz. Alcohol-Free Mouthwash
0.15 oz. net wt. Lip Balm
Hair Brush, Toothbrush, Ear Plugs,
and Kit Case: Made in China
Toothpaste: Made in Thailand

Lot #:

Exp:

Distributed by:

ASP Global, LLC
3450 Atlanta Industrial Parkway
Atlanta, GA 30331

GSHAMEN01 Rev 2

GRACIE
SQUARE
HOSPITAL



Item #: GSHAMEN01

Description: Amenity Kit

PO #:

Lot #: XMMDDFC

Exp: YYYY-MM-DD

Qty: 20 KIT/CS

Carton #: X of XX

Net Wt.: XX KG

Gross Wt.: XX KG

Cubic Dimensions: NN x NN x NN CM

Assembled in China

Components Made in China:

- Shampoo/Conditioner
- Body Wash
- Body Lotion
- Alcohol-Free Mouthwash
- Hair Brush
- Toothbrush
- Ear Plugs
- Lip Balm
- Kit Case

Component Made in Thailand:

- Toothpaste



We are pleased to present this welcome kit for your comfort and convenience during your stay.

Thank you for choosing Gracie Square Hospital for your healthcare!

Contents/Origins:

2.0 fl. OZ. Shampoo/Conditioner

2.0 fl. OZ. Body Wash

2.0 fl. OZ. Body Lotion

2.2 fl. OZ. Alcohol-Free Mouthwash

0.15 oz. net wt. Lip Balm

Hair Brush, Toothbrush, Ear Plugs,

and Kit Case: Made in China

Toothpaste: Made in Thailand

Lot #:

Exp:

Distributed by:

ASP Global, LLC

3450 Atlanta Industrial Parkway

Atlanta, GA 30331

GSHAMEN01 Rev 2



GRACIE SQUARE HOSPITAL AMENITY

sodium monofluorophosphate kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59448-101

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59448-101-00	1 in 1 BAG	01/18/2016	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	10 g
Part 2	1 TUBE	59 mL
Part 3	1 TUBE	59 mL
Part 4	1 TUBE	59 mL
Part 5	1 TUBE	4.25 g
Part 6	1 BOTTLE, PLASTIC	65 mL

Part 1 of 6

COLGATE ANTICAVITY

sodium monofluorophosphate paste, dentifrice

Product Information

Item Code (Source)	NDC:42555-060
Route of Administration	DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	7.6 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Dibasic Calcium Phosphate Dihydrate (UNII: O7TSZ97GEP)	
Water (UNII: 059QF0KO0R)	
Sorbitol (UNII: 506T60A25R)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Sodium Pyrophosphate (UNII: O352864B8Z)	
Saccharin Sodium (UNII: SB8ZUX40TY)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42555-060-45	10 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/04/2009	

Part 2 of 6**GILCHRIST AND SOAMES BODY BUTTER**

cleansing (cold creams, cleansing lotions, liquids, and pads)

Product Information**Route of Administration** TOPICAL**Other Ingredients**

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0K00R)	
INGR	ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
INGR	ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
INGR	BENZYL ALCOHOL (UNII: LKG8494WBH)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
INGR	DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics**color** WHITE C48325**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		59 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		07/01/2013	

Part 3 of 6

GILCHRIST AND SOAMES HAIR 2 IN 1

shampoos (non-coloring)

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	
INGR	SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
INGR	COCO MONOETHANOLAMIDE (UNII: C80684146D)	
INGR	POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 2600000 MW) (UNII: U1G23TFV1K)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
INGR	METHYLCHLOROISO THIAZOLINONE (UNII: DEL7T5QRPN)	
INGR	MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
INGR	METHYL PARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYL PARABEN (UNII: Z8IX2SC1OH)	
INGR	METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
INGR	FD&C RED NO. 4 (UNII: X3W0AMIJLX)	

Product Characteristics

color	YELLOW	C48330
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		59 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		07/01/2013	

Part 4 of 6

GILCHRIST AND SOAMES BODY REFRESHER--BODY WASH

skin fresheners

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	
INGR	SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 260000 MW) (UNII: U1G23TFV1K)	
INGR	CO CO MONOETHANOLAMIDE (UNII: C80684146D)	
INGR	MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
INGR	MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
INGR	METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
INGR	FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
INGR	FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

color GREEN C48329

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		59 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		07/01/2013	

Part 5 of 6

GILCHRIST AND SOAMES MOISTURIZING LIP BALM

lipstick

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	CERESIN (UNII: Q1LS2UJO3A)	
INGR	ETHYLHEXYL PALMITATE (UNII: 2865993309)	
INGR	MINERAL OIL (UNII: T5L8T28FGP)	
INGR	PETROLATUM (UNII: 4T6H12BN9U)	
INGR	HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
INGR	POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
INGR	MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
INGR	CANDELILLA WAX (UNII: WL0328HX19)	
INGR	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
INGR	PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC10H)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
INGR	ACID BLUE 9 AMMONIUM (UNII: 86R7G3C26F)	

Product Characteristics

color YELLOW C48330

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4.25 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		07/01/2013	

Part 6 of 6

ASP GLOBAL, LLC ALCOHOL-FREE

mouthwashes and breath fresheners (liquids and sprays)

Product Information**Route of Administration**

ORAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0K00R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
INGR	SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
INGR	CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
INGR	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

color	BLUE	C48333
flavor	MINT	C73404

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		65 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		07/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/18/2016	

Labeler - ASP Global, LLC (080361159)**Establishment**

Name	Address	ID/FEI	Business Operations
Shengzhou Kingbird Travel Products Co., Ltd.		560219293	PACK(59448-101) , LABEL(59448-101) , REPACK(59448-101)

Establishment

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive (Thailand) LTD		672044552	MANUFACTURE(59448-101)

