BAYLOR SCOTT AND WHITE HYBRID COMFORT- benzalkonium chloride 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.

Baylor Scott & White Hybrid Comfort Kit

Drug Facts

Active Ingredients

Benzalkonium chloride 0.13%

Purpose

Antiseptic

Use

for preparation of the skin prior to an injection.

Warnings

For external use only. Flammable, keep away from fire or flame. Do not use with electrocautery procedures or near eyes. Stop use and ask a doctor if irritation or redness develops.

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

Directions

Apply topically as needed to clean intended area. Discard after single use.

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Disodium EDTA, DMDM Hydantoin, Ethylparaben, Methylparaben, Phenoxyethanol, Polysorbate 20, Sodium Citrate, Water

PRINCIPAL DISPLAY PANEL - Kit Label

BaylorScott&White HEALTH

Item #: BSWHYB01

Description: KIT, BAYLOR SCOTT & WHITE HYBRID COMFORT

PO #:

Lot #: XMMDDFC Exp: YYYY-MM-DD Qty: 20 KIT/CS

Carton #: XXX of XXX
Net Wt.: XX.X KG
Gross Wt.: XX.X KG

Cubic Dimensions: XX x XX x XX CM

Made in China

Components:

- Hand/Body Lotion
- Lip Balm
- Sleep Mask
- Ear Plugs
- Puzzle Book
- Care Book
- Door Hanger
- Playing Cards
- Pen
- Hair Brush
- Stress Ball
- Hand Sanitizing Wipes
- Kit Case

For your comfort and healing, we hope to make your hospital experience as quiet and peaceful as possible. While it is not always feasible to stop all noise as we actively care for our patients, it is our priority to keep noise levels low, especially at night. If we are not meeting your expectations, please let us know. Thank you for trusting Baylor Scott & White with your care!

BaylorScott&White HEALTH

Contents/Origins:

2.0 fl. oz. Hand/Body Lotion 0.15 oz. net wt. Lip Balm Sleep Mask, Ear Plugs, Puzzle Book, Care Book, Door Hanger, Playing Cards, Pen, Hair Brush, Stress Ball, Hand Sanitizing Wipes, and Kit Case: Made in China

Lot #: Exp:

Distributed by: ASP Global, LLC 7800 Third Flag Parkway, Austell, GA 30168, USA

BaylorScott&White HEALTH

REV 00

BaylorScott&White HEALTH



Item #: BSWHYB01

Description: KIT, BAYLOR SCOTT & WHITE HYBRID COMFORT

PO #:

Lot #: XMMDDFC

Exp: YYYY-MM-DD

Qty: 20 KIT/CS

Carton #: XXX of XXX

Net Wt.: XX.X KG

Gross Wt.: XX.X KG

Cubic Dimensions: XX x XX x XX CM

Made in China



Components:

- · Hand/Body Lotion
- · Lip Balm
- Sleep Mask
- · Ear Plugs
- Puzzle Book
- · Care Book
- Door Hanger
- Playing Cards
- Pen
- · Hair Brush
- · Stress Ball
- · Hand Sanitizing Wipes
- · Kit Case

For your comfort and healing, we hope to make your hospital experience as quiet and peaceful as possible. While it is not always feasible to stop all noise as we actively care for our patients, it is our priority to keep noise levels low, especially at night. If we are not meeting your expectations, please let us know. Thank you for trusting Baylor Scott & White with your care!



Contents/Origins:

2.0 fl. OZ. Hand/Body Lotion 0.15 oz. net wt. Lip Balm

Sleep Mask, Ear Plugs, Puzzle Book, Care Book, Door Hanger, Playing Cards, Pen, Hair Brush, Stress Ball, Hand Sanitizing Wipes, and Kit Case: Made in China

Lot #: Exp:

Distributed by: ASP Global, LLC 7800 Third Flag Parkway, Austell, GA 30168, USA



REV 00





PRINCIPAL DISPLAY PANEL - 6.2 g Applicator Label

BaylorScott&White HEALTH OPEN



Drug Facts

Active Ingredients
Benzalkonium chloride 0.13%

Use for preparation of the skin prior to an injection.

Warnings

For external use only. Flammable, keep away from fire or flame. Do not use with electrocautery procedures or near eyes. Stop use and ask a doctor if irritation or redness develops. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Apply topically as needed to clean intended area. Discard after single use.

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Disodium EDTA, DMDM Hydantoin, Ethylparaben, Methylparaben, Phenoxyethanol, Polysorbate 20, Sodium Citrate, Water

Wipe Size 15 x 20 cm

Purpose . Antiseptic

> Manufactured for: ASP Global, LLC 7800 Third Flag Parkway, Austell, GA 30168, USA Made in China

BAYLOR SCOTT AND WHITE HYBRID COMFORT

benzalkonium chloride kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59448-900

| P | Packaging | | | | |
|---|------------------|---------------------|-----------------------------|--------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:59448-900-00 | 1 in 1 BAG | 03/15/2022 | | |

| Quantity of Parts | | | | |
|-------------------|------------------|------------------------|--|--|
| Part # | Package Quantity | Total Product Quantity | | |
| Part 1 | 1 APPLICATOR | 6.2 g | | |
| Part 2 | 1 TUBE | 60 mL | | |
| Part 3 | 1 TUBE | 4.25 g | | |

Part 1 of 3

BENZALKONIUM CHLORIDE

benzalkonium chloride cloth

| Product Information | | |
|-------------------------|---------------|--|
| Item Code (Source) | NDC:59448-010 | |
| Route of Administration | TOPICAL | |

| Active Ingredient/Active Moiety | | | |
|--|--|---------------------------|--------------------|
| Ingredient Name | | Basis of Strength | Strength |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZ UNII:7N6JUD5X6Y) | | BENZ ALKONIUM CHLORIDE | 0.13 g in 100 g |

| Inactive Ingredients | | | |
|---|----------|--|--|
| Ingredient Name | Strength | | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | | | |
| WATER (UNII: 059QF0KO0R) | | | |
| ETHYLPARABEN (UNII: 14255EXE39) | | | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | | | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | | | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | | | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | | | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | | | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | | | |

| ı | Packaging | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|
| 7 | # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| : | NDC:59448- 010-01 | 10 in 1 PACKAGE | | | |
| : | L | 6.2 g in 1 APPLICATOR; Type 0: Not a Combination Product | | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-------------------------|---------------------------------|-----------------|---------------|
| Category | Citation | Date | Date |
| OTC monograph not final | part333E | 02/28/2022 | |

Part 2 of 3

BAYLOR SCOTT WHITE BODY

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

Product Information

| Other Ingredients | | | |
|-------------------|---|----------|--|
| Ingredient Kind | Ingredient Name | Quantity | |
| INGR | WATER (UNII: 059QF0KO0R) | | |
| INGR | MINERAL OIL (UNII: T5L8T28FGP) | | |
| INGR | GLYCERIN (UNII: PDC6A3C0OX) | | |
| INGR | PETROLATUM (UNII: 4T6H12BN9U) | | |
| INGR | DIMETHICONE (UNII: 92RU3N3Y1O) | | |
| INGR | PEG-100 STEARATE (UNII: YD01N1999R) | | |
| INGR | SHEA BUTTER (UNII: K49155WL9Y) | | |
| INGR | STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | | |
| INGR | CETYL ALCOHOL (UNII: 936JST6JCN) | | |
| INGR | GLYCERYL 1-STEARATE (UNII: 258491E1RZ) | | |
| INGR | HYDROXYACETOPHENONE (UNII: G1L3HT4CMH) | | |
| INGR | 1,2-HEXANEDIOL (UNII: TR046Y3K1G) | | |
| INGR | ALLANTOIN (UNII: 344S277G0Z) | | |
| INGR | XANTHAN GUM (UNII: TTV12P4NEE) | | |
| INGR | CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | | |
| INGR | EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | | |
| INGR | SODIUM HYDROXIDE (UNII: 55X04QC32I) | | |

| l | Pa | Packaging | | | | |
|---|----|--------------|--|-------------------------|-----------------------|--|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| | 1 | | 60 mL in 1 TUBE; Type 0: Not a Combination Product | | | |

| Marketing I | Marketing Information | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| Cosmetic | | 03/15/2022 | |
| | | | |

Part 3 of 3

ASP GLOBAL LIP BALM

lipstick

Product Information

| Other Ingredients | | |
|-------------------|---|----------|
| Ingredient Kind | Ingredient Name | Quantity |
| INGR | ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| INGR | MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| INGR | POLYISOBUTYLENE (2300 MW) (UNII: DSQ2V1DD1K) | |
| INGR | YELLOW WAX (UNII: 2ZA36H0S2V) | |
| INGR | HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) | |
| INGR | SHEANUT OIL (UNII: O88E196QRF) | |
| INGR | .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| INGR | PHENOXYETHANOL (UNII: HIE492ZZ3T) | |

Product Characteristics

color WHITE C48325

| l | 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 | | 11/01/2016 | | | | |

| Marketing Information | | | | | |
|-------------------------|---|-------------------------|-----------------------|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | |
| OTC monograph not final | part333E | 03/15/2022 | | | |
| | | | | | |

Labeler - ASP Global, LLc (080361159)

| Establishment | | | | | | | |
|--|---------|-----------|----------------------------|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | |
| Shengzhou Kingbird Travel Products Co., Ltd. | | 560219293 | PACK(59448-900) | | | | |

Revised: 3/2022 ASP Global, LLc