

SECURA EPC SKIN CARE STARTER KIT- zinc oxide, benzethonium chloride
Smith & Nephew Medical 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.

Secura EPC Skin Care Starter Kit

☐#59434100

NDC 69740-341-00

EPC Skin Care Starter Kit

☐Good skin care can help prevent breakdown.

DIRECTIONS

1. Change wet and soiled diapers, garments, and linens promptly. Spray cleanser liberally on affected area.
2. Wipe clean with tissues, and remove soiled underpads and diapers.
3. Immediately dispose of tissues and underpads to control odor. Allow to dry. No rinsing necessary.
4. Apply protective cream liberally as often as necessary with each diaper, garment, or linen change; especially at bedtime or anytime when exposure to soiled diapers, garments, linens, feces or urine may be prolonged.
5. Check patient often. Repeat steps 1-4 after each exposure to feces and urine.

Refer to individual product labeling for detailed instructions.

Packaged in the USA with products made in USA and India for:

Smith & Nephew Medical Ltd, 101 Hessle Road, Hull HU3 2BN England.

www.smith-nephew.com

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DRUG FACTS - SECURA◇ MOISTURIZING CLEANSER

ACTIVE INGREDIENT

Benzethonium chloride 0.13%

PURPOSE

Antimicrobial

USES

- Antimicrobial skin cleanser for the perineum or body
- Aids in the removal of urine and feces, or other foreign material

WARNINGS

- **For external use only**
- **Avoid contact with the eyes**

- **Not to be applied** over deep or puncture wounds, infections or lacerations
- **If condition worsens** or does not improve within 7 days, contact a doctor
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately

DIRECTIONS

- apply liberally on affected area, then wipe clean
- no rinsing necessary

INACTIVE INGREDIENTS

water, polysorbate 20, glycerin, polyquaternium-10, benzyl alcohol, fragrance, disodium EDTA, aloe barbadensis, FD&C Blue #1

QUESTIONS OR COMMENTS?

☎1 800 876-1261

DRUG FACTS - SECURA◇ EXTRA PROTECTIVE CREAM

ACTIVE INGREDIENT

Zinc Oxide 30.6%

PURPOSE

Skin protectant

USES

- helps treat and prevent diaper dermatitis
- protects minor skin irritation associated with diaper dermatitis and helps seal out wetness

WARNINGS

- **For external use only**
- **Avoid contact with the eyes**
- **Not to be applied** over deep or puncture wounds, infections or lacerations
- **If condition worsens** or does not improve within 7 days, contact a doctor
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately

DIRECTIONS

- change wet and soiled diapers, garments, and linens promptly
- cleanse the affected area and allow to dry

- apply cream liberally as often as necessary with each diaper change; especially at bedtime or anytime when exposure to soiled diapers, garments, linens, feces or urine may be prolonged

OTHER INFORMATION

Store at controlled room temperature 59°F-86°F (15°C-30°C)

INACTIVE INGREDIENTS

petrolatum, karaya gum, cetearyl alcohol, methyl glucose dioleate, mineral oil, cellulose gum, water, methylparaben, tocopheryl acetate, diazolidinyl urea, benzethonium chloride, butylparaben

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - SECURA EPC SKIN CARE STARTER KIT

#59434100

NDC 69740-341-00

EPC Skin Care Starter Kit

Kit contains:

Antimicrobial Skin Cleanser

Secura◇ Moisturizing Cleanser

4 fl. oz. (118 mL)

- No-rinse, one-step cleansing for perineum or body
- Gently removes urine, feces, and other body fluids
- Reduces odor
- pH-buffered
- Pediatric tested
- CHG compatible

Skin Protectant

Secura◇ Extra Protective Cream

3.25 oz. (92 g)

- For treatment and prevention of incontinence-associated dermatitis
- For use on denuded skin associated with exposure to feces or urine
- Adheres to macerated skin
- Pediatric tested
- CHG compatible

Smith&Nephew

Secura◇

EPC Skin Care Starter Kit



EPC Skin Care Starter Kit

NDC 69740-341-00
REF 59434100

REF 59434100
NDC 69740-341-00

EPC Skin Care Starter Kit

Good skin care can help prevent breakdown.



1. Change wet and soiled diapers, garments, and linens promptly. Spray cleanser liberally on affected area.



2. Wipe clean with tissues, and remove soiled underpads and diapers.



3. Immediately dispose of tissues and underpads to control odor. Allow to dry. No rinsing necessary.



4. Apply protective cream liberally as often as necessary with each diaper, garment, or linen change; especially at bedtime or anytime when exposure to soiled diapers, garments, linens, feces or urine may be prolonged.



5. Check patient often. Repeat steps 1-4 after each exposure to feces and urine.

Refer to individual product labeling for detailed instructions.

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SECURA® Moisturizing Cleanser

Drug Facts

Active ingredient Purpose
Benzethonium chloride 0.13% ... Antimicrobial

Uses
■ Antimicrobial skin cleanser for the perineum or body
■ Aids in the removal of urine and feces, or other foreign material

Warnings
For external use only
Avoid contact with the eyes
Not to be applied over deep or puncture wounds, infections or lacerations
If condition worsens or does not improve within 7 days, contact a doctor
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately

Directions
■ Apply liberally on affected area, then wipe clean
■ No rinsing necessary

Inactive ingredients: water, polysorbate 20, glycerin, polyquaternium-10, benzyl alcohol, fragrance, disodium EDTA, aloe barbadensis, FD&C Blue #1

Questions or comments?
1-800-876-1261

SECURA® Extra Protective Cream

Drug Facts

Active ingredient Purpose
Zinc oxide 30.8% ... Skin protectant

Uses
■ Helps treat and prevent diaper dermatitis
■ Protects minor skin irritation associated with diaper dermatitis and helps seal out wetness

Warnings
For external use only
Avoid contact with the eyes
Not to be applied over deep or puncture wounds, infections or lacerations
If condition worsens or does not improve within 7 days, contact a doctor
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately

Directions
■ Change wet and soiled diapers, garments, and linens promptly
■ Cleanse the affected area and allow to dry
■ Apply cream liberally as often as necessary with each diaper change, especially at bedtime or anytime when exposure to soiled diapers, garments, linens, feces or urine may be prolonged

Other information Store at controlled room temperature 59°F-86°F (15°C-30°C)

Inactive ingredients: petrolatum, karaya gum, cetylalcohol, methyl glucose dioleate, mineral oil, cellulose gum, water, methylparaben, tocopheryl acetate, diazolidinyl urea, benzethonium chloride, butylparaben



REF 59434100
NDC 69740-341-00

EPC Skin Care Starter Kit

Kit contains:

Antimicrobial Skin Cleanser

SECURA® Moisturizing Cleanser
4 fl. oz. (118 mL)

- No-rinse, one-step cleansing for perineum or body
- Gently removes urine, feces, and other body fluids
- Reduces odor
- pH-buffered
- Pediatric tested
- CHG compatible

Skin Protectant

SECURA® Extra Protective Cream
3.25 oz. (92 g)

- For treatment and prevention of incontinence-associated dermatitis
- For use on denuded skin associated with exposure to feces or urine
- Adheres to macerated skin
- Pediatric tested
- CHG compatible



SECURA®
EPC Skin Care Starter Kit

PACKAGE LABEL - SIDE DISPLAY PANEL - SECURA EPC SKIN CARE STARTER KIT

#59434100

NDC 69740-341-00

EPC Skin Care Starter Kit

Kit contains:

Secura◇ Moisturizing Cleanser
4 fl. oz. (118 mL)

Secura◇ Extra Protective Cream
3.25 oz. (92 g)

Smith&Nephew

Secura◇

EPC Skin Care Starter Kit

REF 59434100
NDC 69740-341-00

EPC Skin Care Starter Kit

Kit contains:

SECURA◇ Moisturizing Cleanser
4 fl. oz. (118 mL)

SECURA◇ Extra Protective Cream
3.25 oz. (92 g)





PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - SECURA EXTRA PROTECTIVE CREAM - TUBE (92 g)

Item #59432400

NDC 69740-324-00

Extra Protective Cream

Skin Protectant

- For treatment and prevention of incontinence-associated dermatitis
- For use on denuded skin associated with exposure to feces or urine
- Adheres to macerated skin
- Pediatric tested
- CHG compatible

Smith & Nephew

Secura◇

Extra Protective Cream

Net wt. 3.25 oz. (92 g)

DRUG FACTS

ACTIVE INGREDIENT

□Zinc Oxide 30.6%

□**PURPOSE**

Skin protectant

□**USES**

- skin protectant
- helps treat and prevent diaper dermatitis
- protects minor skin irritation associated with diaper dermatitis and helps seal out wetness

ⓧWARNINGS

- **For external use only**
- **Avoid contact with the eyes**

- **Not to be applied** over deep or puncture wounds, infections or lacerations

- **If condition worsens** or does not improve within 7 days, contact a doctor

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

ⓧDIRECTIONS

- change wet and soiled diapers, garments, and linens promptly
- cleanse the affected area and allow to dry
- apply cream liberally as often as necessary with each diaper change; especially at bedtime or anytime when exposure to soiled diapers, garments, linens, feces or urine may be prolonged

ⓧOTHER INFORMATION

Store at controlled room temperature 59°F-86°F (15°C-30°C)

ⓧINACTIVE INGREDIENTS

petrolatum, karaya gum, cetearyl alcohol, methyl glucose dioleate, mineral oil, cellulose gum, water, methylparaben, tocopheryl acetate, diazolidinyl urea, benzethonium chloride, butylparaben

ⓧQuestions or comments?

ⓧ1 800 876-1261

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Drug Facts

Active Ingredient	Purpose
Zinc oxide 30.6%	Skin protectant

Uses ■ skin protectant ■ helps treat and prevent diaper dermatitis ■ protects minor skin irritation associated with diaper dermatitis and helps seal out wetness

Warnings

For external use only

Avoid contact with the eyes

Not to be applied over deep or puncture wounds, infections or lacerations

If condition worsens or does not improve within 7 days, contact a doctor

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

Directions ■ change wet and soiled diapers, garments and linens promptly
 ■ cleanse the affected area and allow to dry
 ■ apply cream liberally as often as necessary with each diaper change; especially at bedtime or anytime when exposure to soiled diapers, garments, linens, feces or urine may be prolonged

Other Information Store at controlled room temperature 59°F-86°F (15°C-30°C)

Inactive Ingredients petrolatum, karaya gum, cetearyl alcohol, methyl glucose dioleate, mineral oil, cellulose gum, water, methylparaben, tocopheryl acetate, diazolidinyl urea, benzethonium chloride butylparaben

Questions or comments? 1 800 876-1261

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56298



GO/DRUGS/361

Room #

Name

EPC

REF 59432400
NDC 69740-324-00

Extra Protective Cream

Skin Protectant

- For treatment and prevention of incontinence-associated dermatitis
- For use on denuded skin associated with exposure to feces or urine
- Adheres to macerated skin
- Pediatric tested
- CHG compatible

 **smith&nephew**
SECURA°

Extra Protective Cream

Net wt. 3.25 oz. (92 g)

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - SECURA MOISTURIZING CLEANSER - BOTTLE (118 mL)

Item #59430800

NDC 69740-308-00

Moisturizing Cleanser

Antimicrobial Skin Cleanser

- No-rinse, one-step cleansing for perineum or body

- Gently removes urine, feces, and other body fluids
- Reduces odor
- pH-balanced
- Pediatric tested
- CHG compatible

Smith&Nephew

Secura◇

Moisturizing Cleanser

4 fl. oz. (118 mL)

▯DRUG FACTS

▯ACTIVE INGREDIENT

Benzethonium chloride 0.13%

▯PURPOSE

Antimicrobial

▯USES

- antimicrobial skin cleanser for the perineum or body
- aids in the removal of urine and feces, or other foreign material

▯WARNINGS

- **For external use only**
- **Avoid contact with eyes**

• **Not to be applied** over deep or puncture wounds, infections or lacerations

• **If condition worsens or does not improve** within 7 days, contact a doctor

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

▯DIRECTIONS

- apply cleanser liberally on affected area, then wipe clean
- no rinsing necessary

▯INACTIVE INGREDIENTS

water, polysorbate 20, glycerin, polyquaternium-10, benzyl alcohol, fragrance, disodium EDTA, aloe barbadensis, FD&C Blue #1

▯QUESTIONS OR COMMENTS?

▯1 800 876-1261

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REF 59430800
NDC 69740-308-00

Moisturizing Cleanser

Antimicrobial Skin Cleanser

- No-rinse, one-step cleansing for perineum or body
- Gently removes urine, feces, and other body fluids
- Reduces odor
- pH-balanced
- Pediatric tested
- CHG compatible



SECURA[◇]
Moisturizing Cleanser
4 fl. oz. (118 mL)

Drug Facts

Active ingredient	Purpose
Benzethonium chloride 0.13%	Antimicrobial

Uses ■ antimicrobial skin cleanser for the perineum or body
■ aids in the removal of urine and feces, or other foreign material

Warnings
For external use only

Avoid contact with eyes

Not to be applied over deep or puncture wounds, infections or lacerations

If condition worsens or does not improve within 7 days, contact a doctor

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Directions ■ apply cleanser liberally on affected area, then wipe clean ■ no rinsing necessary

Inactive ingredients water, polysorbate 20, glycerin, polyquaternium-10, benzyl alcohol, fragrance, disodium EDTA, aloe barbadensis, FD&C Blue #1

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59905



Room #

Name

SECURA EPC SKIN CARE STARTER KIT

zinc oxide, benzethonium chloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69740-341
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69740-341-00	1 in 1 CONTAINER	08/01/2003	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	92 g
Part 2	1 BOTTLE, SPRAY	118 mL

Part 1 of 2

SECURA EXTRA PROTECTIVE

zinc oxide cream

Product Information

Item Code (Source) NDC:69740-324

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	306.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	30.6 mg in 1 g
WATER (UNII: 059QF0KO0R)	21.6 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U)	408.2 mg in 1 g
MINERAL OIL (UNII: T5L8T28FGP)	41 mg in 1 g
METHYLPARABEN (UNII: A2I8C7HI9T)	3.1 mg in 1 g
KARAYA GUM (UNII: 73W9IQY50Q)	71.4 mg in 1 g
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	2 mg in 1 g
BUTYLPARABEN (UNII: 3QP1I1U3FV8)	0.5 mg in 1 g
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	1.3 mg in 1 g
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	2 mg in 1 g
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	61.2 mg in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		92 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347		

Part 2 of 2

SECURA MOISTURIZING CLEANSER

benzethonium chloride spray

Product Information

Item Code (Source)	NDC:69740-308
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	1.3 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	0.05 ug in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	2 uL in 1 mL
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.2 ug in 1 mL
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.001 ug in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	10 ug in 1 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	30 ug in 1 mL
WATER (UNII: 059QF0K00R)	945.94 uL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		118 mL in 1 BOTTLE, SPRAY; 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	part333E		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/01/2003	

Labeler - Smith & Nephew Medical Ltd (216344051)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-America Products, Inc.		080170933	manufacture(69740-308, 69740-341)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 12/2017

Smith & Nephew Medical Ltd