

D-COL PERSONAL HYGIENE CONVENIENCE KIT- pyrrithione zinc and chloroxylenol
D-COL 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.

D-COL Personal Hygiene Convenience Kit

D-COL Patient Antiseptic Skin Preparation

Drug Facts

Active Ingredient

Chloroxylenol 0.24%

Purpose

Antiseptic

Uses

- Antiseptic skin cleansers help reduce bacteria that potentially causes disease.
- For patient antiseptic skin preparation (15 mL packets only).
- For healthcare personnel hand wash.
- For surgical hand scrub.

Do not use

- If you or the patient is allergic to Chloroxylenol or any other ingredient in this product.

When using this product

- Keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.
- If contact occurs in any of these areas, rinse with cold water right away.
- Repeated general cleansing of large body areas should not be done except when advised by a health care provider.

Stop use and ask doctor if irritation, sensitization, or allergic reaction occurs.

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

Directions

- *Patient antiseptic skin preparation.* Thoroughly rinse the area to be cleansed with water. Apply the minimum amount of the product necessary to cover the skin area

and wash gently. Rinse thoroughly with water.

- *Surgical hand scrub.* Wet hands and forearms with water. Scrub for 3 minutes with about 5 mL of the product with a brush. Rinse thoroughly under running water.
- *Healthcare personnel handwash.* Wet hands with water. Dispense about 5 mL of the product into cupped hands and wash in a vigorous manner for 15 seconds. Rinse and dry thoroughly.

Other Information

- Store between 20-25°C (68-77°F).
- Avoid excessive heat above 40°C (104°F).

Inactive Ingredient

propylene glycol, cocamide dea, ammonium lauryl sulfate, sodium laureth sulfate, citric acid, edta, ammonium chloride, propylparaben, imidazolidinyl urea, fragrance, deionized water

Net Wt. 15 mL per packet

Distributed by: D-COL, Inc. 219 East Craig Place San Antonio, TX 78212

Questions?

(210)-227-3612

D-COL Nasal Inner Rim Cleanser

Uses

For nasal inner rim cleanser.

Warnings

For use only in the inner rim of each nostril.

When using this product

Avoid contact with eyes. In case of eye contact, flush with water.

Stop use and ask doctor if irritation, discomfort, or redness develops.

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

Directions

- Apply a reasonable amount of the product to the end of your index finger for a single nasal inner rim application.
- Save a reasonable amount to apply to the opposite nasal inner rim.
- Insert your index finger into one nostril no further than the inner rim, and cover the

inner rim of the nasal passage with the product.

- Do not apply the product beyond the inner rim of the nasal passage.
- Repeat the application of the product to the untreated nasal inner rim.
- Wait 30 seconds after you complete the application, and thoroughly wipe the inner rim of each nostril with a cloth wet with water.
- Children under 6 years of age should be supervised when using this product.

Inactive Ingredient

benzalkonium chloride, polysorbate 20, peach kernel oil glycereth-8 esters, sodium chloride, potassium sorbate, sodium citrate, xylitol, disodium edta, lavandula angustifolia (lavender) oil, mentha viridis (spearmint leaf) oil, melaleuca alternifolia (tea tree leaf) oil, citric acid

Net Wt. 1 mL per packet

Distributed by: D-COL, Inc. 219 East Craig Place San Antonio, TX 78212

Questions?

(210)-227-3612

D-COL Shampoo

Drug Facts

Active Ingredient

Zinc Pyrithione 1.0%

Purpose

Anti-dandruff

Uses

helps prevent recurrence of flaking and itching associated with dandruff.

Warnings

For external use only.

When using this product

Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask doctor if condition worsens or does not improve after regular use of this product as directed.

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

Directions

- Place enough product in your palm to thoroughly cover the scalp area.
- Rub hands together until product covers entire surface of your palms.
- Apply product to the scalp and thoroughly massage and cover the scalp.
- Rinse with water until the product is completely removed from the application area.
- Use one packet as directed.
- Children under 6 years of age should be supervised when using this product.

Inactive Ingredient

deionized water, acrylates/C10-30 alkyl acrylate crosspolymer, sodium lauryl ether sulfate, PEG-90 diisostearate, cocamidopropyl betaine, cocamide dea, cyclomethicone 5, edta sodium, caprylyl glycol, sodium hydroxide

Net Wt. 7.4 mL per packet

Distributed by: D-COL, Inc. 219 East Craig Place San Antonio, TX 78212

Questions?

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PRINCIPAL DISPLAY PANEL - Kit Carton Label

DCOL

Personal Hygiene
Convenience Kit

Patient Antiseptic Skin Preparation
Chloroxylenol .24%
(3 count, Net Wt. 15 mL Per Packet)

Shampoo
Zinc Pyrithione 1.0%
(3 count, Net Wt. 7.4 mL Per Packet)

Nasal Inner Rim Cleanser
Organic
(1 count, Net Wt. 1 mL)

Compare to active ingredient in Hibiclens: FDA:
Chlorhexidine Gluconate can cause rare but serious life
threatening allergic reaction.

Single Use Packets

DCOL

Personal Hygiene Convenience Kit

Patient Antiseptic Skin Preparation

Chloroxylenol .24%

(3 count, Net Wt. 15 mL Per Packet)

Shampoo

Zinc Pyrithione 1.0%

(3 count, Net Wt. 7.4 mL Per Packet)

Nasal Inner Rim Cleanser

Organic

(1 count, Net Wt. 1 mL)

Compare to active ingredient in Hibiclens: FDA:
Chlorhexidine Gluconate can cause rare but serious life
threatening allergic reaction.

Single Use Packets

D-COL PERSONAL HYGIENE CONVENIENCE KIT

pyrithione zinc and chloroxylenol kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53205-001
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53205-001-01	1 in 1 CARTON	05/30/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	3 PACKET	22.2 mL

Part 2	3 PACKET	45 mL
Part 3	1 PACKET	1 mL

Part 1 of 3

D-COL

pyrithione zinc shampoo

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pyrithione Zinc (UNII: R953O2RHZ5) (Pyrithione Zinc - UNII:R953O2RHZ5)	Pyrithione Zinc	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
PEG-90 Diisostearate (UNII: YAE61SLW68)	
Cocamidopropyl Betaine (UNII: 5OCF3O11KX)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.4 mL 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 FINAL	part358H	05/30/2018	

Part 2 of 3

D-COL PATIENT ANTISEPTIC SKIN PREPARATION

chloroxylenol soap

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Chloroxylenol (UNII: 0F32U78V2Q) (Chloroxylenol - UNII:0F32U78V2Q)	Chloroxylenol	2.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Propylene Glycol (UNII: 6DC9Q167V3)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
Ammonium Lauryl Sulfate (UNII: Q7AO2R1M0B)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETIC ACID (UNII: 9G34HU7RV0)	
Ammonium Chloride (UNII: 01Q9PC255D)	
Propylparaben (UNII: Z8IX2SC1OH)	
IMIDUREA (UNII: M629807ATL)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		15 mL 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	05/30/2018	

Part 3 of 3

D-COL NASAL INNER RIM CLEANSER

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

Product Information

Route of Administration NASAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Benzalkonium Chloride (UNII: F5UM2KM3W7)	
INGR	Polysorbate 20 (UNII: 7T1F30V5YH)	
INGR	Peach Kernel Oil Glycereth-8 esters (UNII: RY37QKW66H)	
INGR	Sodium Chloride (UNII: 451W47IQ8X)	
INGR	Potassium Sorbate (UNII: 1VPU26JZZ4)	
INGR	SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
INGR	Xylitol (UNII: VCQ006KQ1E)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	LAVENDER OIL (UNII: ZBP1YXW0H8)	
INGR	SPEARMINT OIL (UNII: C3M81465G5)	
INGR	TEA TREE OIL (UNII: VIF565UC2G)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL 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
COSMETIC		05/30/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part358H	05/30/2018	

Labeler - D-COL Inc (829947329)

Establishment

Name	Address	ID/FEI	Business Operations
Identipak, Inc.		942862350	MANUFACTURE(53205-001) , PACK(53205-001)

