DERMACINRX SURGICAL COMBOPAK- chlorhexidine gluconate surgical combo kit
PureTek Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

DermacinRx Surgical ComboPak

PART 1: Chlorhexidine Gluconate

Drug Facts

Active ingredient

Chlorhexidine Gluconate 4% solution

Purpose

Antiseptic

Uses

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash:** helps reduce bacteria that potentially can cause disease
- **patient preoperative skin preparation:** for the preparation of the patient's skin prior to surgeryskin wound and general skin cleansing
- **skin wound and general skin cleansing**

Warnings

For external use only

Do not use

- if you are allergic to chlorhexidine gluconate or any other ingredients
- in contact with meninges
- in the genital area
- as a preoperative skin preparation of the head or face

When using this product

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures or may cause deafness when instilled in the middle ear through perforated eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be

routinely treated
- repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population of skin

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

Directions

use with care in premature infants and infants under 2 months of age. These products may cause irritation or chemical burns.

- **Surgical hand scrub:**
  - wet hands and forearms with water
  - scrub for 3 minutes with about 5 ml of product and a wet brush paying close attention to the nails, cuticles and interdigital spaces
  - a separate nail cleaner may be used
  - rinse thoroughly
  - wash for an additional 3 minutes with 5 ml of product and rinse under running water
  - dry thoroughly
- **Healthcare personnel handwash:**
  - wet hands with water
  - dispense about 5 ml of product into cupped hands and wash in a vigorous manner for 15 seconds
  - rinse and dry thoroughly
- **Patient preoperative skin preparation:**
  - apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel
  - repeat procedure for an additional 2 minutes and dry with a sterile towel
- **Skin wound and general skin cleaning:**
  - thoroughly rinse the area to be cleaned with water
  - apply the minimum amount of product necessary to cover the skin or wound area and wash gently
  - rinse again thoroughly

Other information

- store at 20-25ºC (68-77ºF)
- avoid excessive heat above 40ºC (104ºF)

Inactive ingredients

cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol

PART 2: Skin Repair Complex

Drug Facts

Active ingredient

Dimethicone 5.0%

Uses

■ for the treatment and/or prevention of diaper rash
■ temporarily protects and helps relieve chapped or cracked skin

Warnings

For external use only

Do not use on ■ deep or puncture wounds ■ animal bites ■ serious burns

When using this product ■ do not get into eyes

Stop use and ask a doctor if■ condition worsens
■ symptoms last more than 7 days or clear up and occur again within a few days

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

Directions

■ apply cream liberally as needed

Other information

■ protect from freezing ■ avoid excessive heat

Inactive ingredients

Aleurites moluccana seed oil, *Aloe barbadensis* (*Aloe vera*) leaf juice, butylene glycol, caprylyl glycol, *Carthamus tinctorius* (safflower) seed oil, cetyl alcohol, chlorphenesin, dimethicone crosspolymer, disodium EDTA, fragrance, glycerin, glyceryl stearate, DermacinRx Complex ® [consisting of: bisabolol, calcium pantothenate (vitamin B_5), *Carthamus tinctorius* (safflower) oleosomes, maltodextrin, niacinamide (vitamin B_3), pyridoxine HCl (vitamin B_6), silica, sodium ascorbyl phosphate (vitamin C), sodium starch octenylsuccinate, tocopheryl acetate (vitamin E), *Zingiber officinale* (ginger) root extract], PEG-100 stearate, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, phenoxyethanol, purified water, sodium hyaluronate, stearic acid, triethanolamine.

PART 3: Silicone Tape

Uses

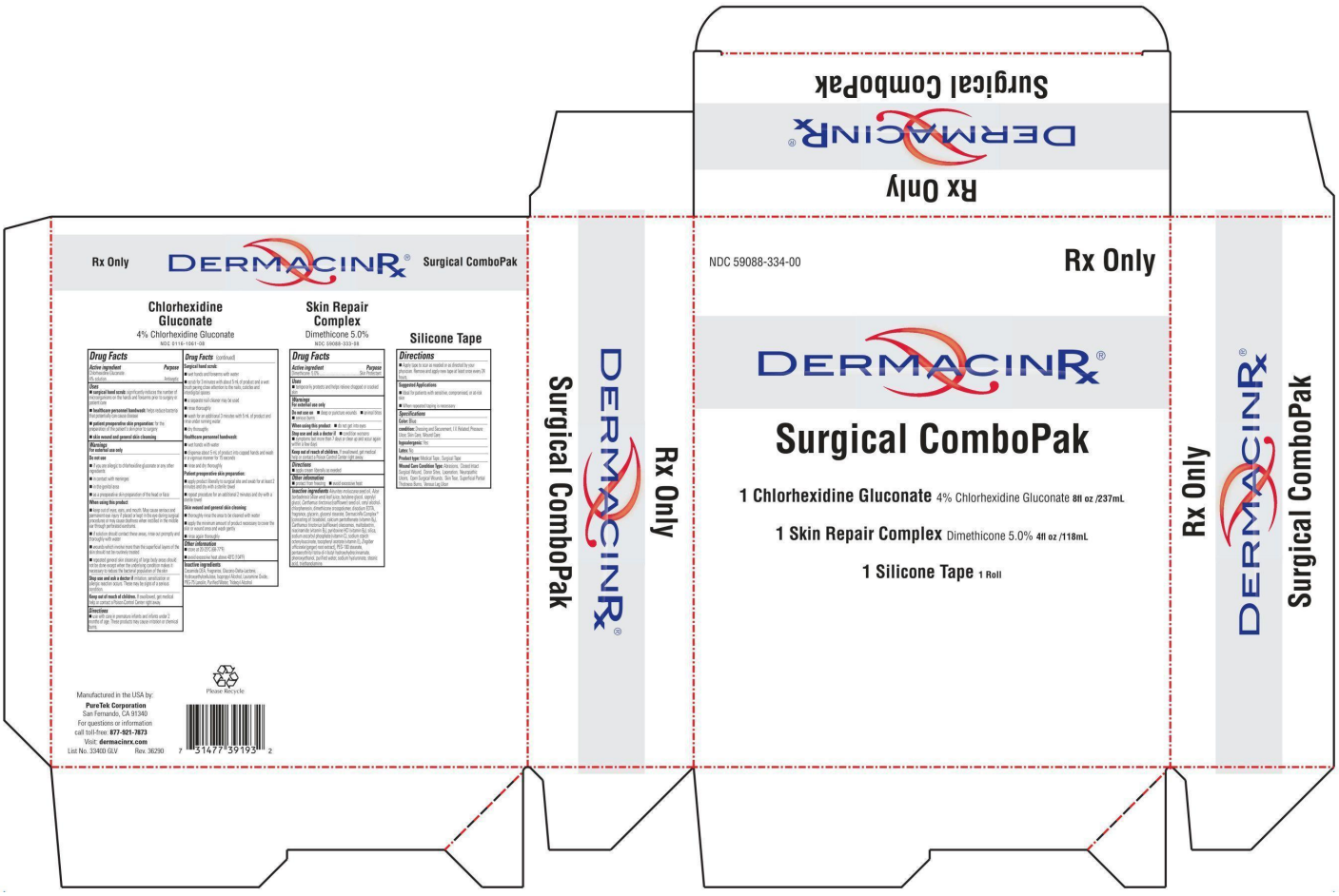
• To be applied to wounds or scars as a protective silicone barrier.
• As a dressing for abrasions, surgical wounds, donor sites, lacerations, ulcers, skin tears, superficial partial thickness burns, venous leg ulcers.
• As a dressing/securement for IV related uses, pressure ulcers, skin care, and wound care

Precautions

• Do not use if you are allergic to silicone
• Keep out of reach of children

Directions for use

• Apply tape to wound or scar as needed or as directed by your physician. Remove tape, wash area, and apply new tape at least every 24 hours.



DERMACINRX SURGICAL COMBOPAK

chlorhexidine gluconate surgical combo kit kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-334

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:59088-334-00	1 in 1 PACKAGE; Type 0: Not a Combination Product	04/28/2015	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, PLASTIC	237 mL
Part 2	1 TUBE	118 mL

Part 1 of 2

ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate solution

Product Information	
Item Code (Source)	NDC:0116-1061
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
WATER (UNII: 059QF0KO0R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0116-1061-08	237 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
NDA	NDA019125		

Part 2 of 2

SKIN REPAIR COMPLEX

dimethicone cream

Product Information

Item Code (Source)	NDC:59088-333
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
KUKUI NUT OIL (UNII: TP11QR7B8R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE/DIENE DIMETHICONE CROSSPOLYMER (UNII: RSA9I561OK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LEVOMENOL (UNII: 24WE03BX2T)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
GINGER (UNII: C5529G5JPQ)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

WATER (UNII: 059QF0KO0R)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-333-08	118 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
OTC monograph final	part347		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/28/2015	

Labeler - PureTek Corporation (785961046)

Registrant - PureTek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	pack(59088-334) , manufacture(59088-333)

Revised: 1/2023 PureTek Corporation