

BETASEPT- antiseptic surgical scrub solution
Avrio Health L.P.

BETASEPT Antiseptic Surgical Scrub

Chlorhexidine Gluconate 4%

Drug Facts

Active ingredient Purpose

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
- **skin wound and general skin cleansing**

Warnings

For external use only

- **Allergy alert:** This product may cause a severe allergic reaction. Symptoms may include: wheezing/difficulty breathing
- Shock
- facial swelling
- hives
- rash. If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with meninges
- in the genital area

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 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 advised by a health care provider

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 or 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
- dry with a sterile towel
- repeat procedure for an additional 2 minutes and dry with a sterile towel

Skin wound and general skin cleansing:

- 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 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

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

Questions or comments? call 1-888-827-0624

Dist. by: **Avrio Health L.P. Stamford, CT 06901-3431**

304978-0A

BETASEPT

Antiseptic Surgical Scrub

NDC: 67618-200-30

NDC 67618-200-30

For External Use Only
Not for Retail Sale
For Professional and Hospital Use Only

BETASEPT[®]

Antiseptic Surgical Scrub



Chlorhexidine Gluconate 4%



Net Contents:
32 fl oz (946 mL)

Dist. by:
Avrio Health L.P.
Stamford, CT 06901-3491 304879-0A

4BET32BTL18L8

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
■ skin wound and general skin cleansing

Warnings

For external use only

Allergy alert: This product may cause a severe allergic reaction. Symptoms may include: ■ wheezing/difficulty breathing ■ shock ■ facial swelling ■ hives ■ rash. If an allergic reaction occurs, stop use and seek medical help right away.

Do not use ■ if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
■ in contact with meninges ■ in the genital area

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 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 advised by a health care provider

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 or 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

Skin wound and general skin cleansing: ■ 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 20-25°C (68-77°F) ■ avoid excessive heat above 40°C (104°F)

Inactive ingredients cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, triethyl alcohol.

Questions or comments? call 1-888-827-0824 (8am-5pm, EST, Mon-Fri.)

WARNING: This product can expose you to chemicals including coconut oil diethanolamine condensate (cocamide diethanolamine), which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov

BETASEPT

antiseptic surgical scrub solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67618-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Chlorhexidine Gluconate (UNII: MOR84MUD8E) (Chlorhexidine - UNII:R4KO0DY52L)	Chlorhexidine Gluconate	.04 mg in 1 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: 059QF0K00R)	
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:67618-200-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993	
2	NDC:67618-200-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993	
3	NDC:67618-200-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993	

4	NDC:67618-200-30	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993	
5	NDC:67618-200-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993	
6	NDC:67618-200-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1993	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	06/01/1993	

Labeler - Avrio Health L.P. (141916531)

Registrant - Purdue Pharma LP (932323652)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	MANUFACTURE(67618-200)

Revised: 10/2018

Avrio Health L.P.