BIOSHELL- cetylpridinium chloride spray
BioFilm, 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.

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Active ingredients

Cetylpridinium Chloride 0.1% -- Oral Antiseptic

Purpose

Oral Antiseptic

Uses

First aid to help prevent infection in minor oral irritations

Warnings

- Discontinue use and see your dentist or doctor promptly if sore mouth symptoms do not improve in 7 days, if irritation pain, or redness persists or worsens, or if swelling, rash, or fever develops.
- Do not use children under 12 years of age
- Keep out of reach of children
- If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 12 years of age and older: spray into mouth where irritation is present 1 to 3 times, or spray and swish the liquid to affected areas. Expectorate any residual liquid. Use up to 3 times a day, or as directed by a dentist or doctor.
- Children under 12 years of age: consult a dentist or physician.

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN UNDER 6 YEARS OF AGE.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Contol Center right away.

Other Information

Store between 15C and 30C (59F to 86F)

Inactive ingredients

Purified water, Glycerin, Xylitol, PEG-60 Hydrogenated Castor Oil, PVP-VA S-630 Copolymer, Sodium Benzonate USP/NF/FCC, Potassium Sorbate NF, Xanthan Gum, Sodium Saccharin, Berry Flavor.

Questions or Comments?

Call toll-free 1-800-848-5900

BioShell

BIOSHELL

cetylpridinium chloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66357-120
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7JI0JV3)	CETYLPYRIDINIUM CHLORIDE	0.1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	
PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66357-120-02	1 in 1 BOX	05/02/2022	
1	NDC:66357-120-01	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/02/2022	

Labeler - BioFilm, Inc. (790780258)

Establishment

Name	Address	ID/FEI	Business Operations
BioFilm, Inc.		790780258	manufacture(66357-120)

Revised: 3/2022 BioFilm, Inc.