

STERAL ANTISEPTIC SANITIZING WIPE- benzalkonium chloride cloth
STERAL PRODUCTS LIMITED

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.

BENZALKONIUM CHLORIDE ANTISEPTIC SANITIZING WIPE

Drug Facts

Active Ingredient

Benzalkonium chloride 0.075% w/v

Purpose

Antiseptic

Uses

• hand sanitizing wipe to decrease bacteria on skin • for use when soap and water are not available

Warnings

For external use only.

Do not use • in children less than 2 months of age • on open skin wounds

When using this product • do not get into eyes.

In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if • irritation and redness develop • condition persist for more than 72 hours • there are symptoms of serious allergic reactions.

Contains chlorhexidine digluconate.

If pregnant or breast-feeding, ask a health professional before use.

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

Directions

• wet hands thoroughly with product and allow to dry without wiping • supervise children under 6 years of age when using this product to avoid swallowing • discard after use • do not dispose of wipes in flush toilet

Other information

- store between 15-30°C (59-86°F)

Inactive ingredients

Chlorhexidine Digluconate, Didecyldimethylammonium Chloride, Ethyl Alcohol, Lauramine Oxide, p-Chloro-m-Cresol, Propylene Glycol, Water (Aqua)

Questions?

+1-XXX-XXX-XXXX

You may also report serious side effects to this phone number. Mon - Fri 9:00 AM - 5:00 PM

1 Wipe

Size 7.87 in x 5.91 in (200 mm x 150 mm)

Manufactured by: Steral Products Ltd
Unit 1 Easter Court, Warrington,
United Kingdom, WA5 7ZB

(MADE IN UK)

Lot No.:

Expiry Date:

info@steral.com

Packaging



Drug Facts		Drug Facts (continued)
Active ingredient Benzalkonium chloride 0.075% w/v.....	Purpose Antiseptic	Directions • wet hands thoroughly with product and allow to dry without wiping • supervise children under 6 years of age when using this product to avoid swallowing • discard after use • do not dispose of wipes in flush toilet
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		Lot No.: Expiry Date: Info@steral.com

STERAL ANTISEPTIC SANITIZING WIPE

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82045-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.75 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B)	
ALCOHOL (UNII: 3K9958V90M)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
CHLOROCRESOL (UNII: 36W53O7109)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82045-050-01	1 in 1 PACKET	07/12/2021	
1		2.9 mL in 1 PACKAGE; 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	part333A	07/12/2021	

Labeler - STERAL PRODUCTS LIMITED (227818160)

Establishment			
Name	Address	ID/FEI	Business Operations
STERAL PRODUCTS LIMITED		227818160	manufacture(82045-050)

Revised: 7/2021

STERAL PRODUCTS LIMITED