ANTIBACTERIAL WIPES UNSCENTED- benzethonium chloride solution ZHANGZHOU WANSIKE ELECTRONICS CO., LTD

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.

80593-008 ANTIBACTERIAL WIPES UNSCENTED

Active Ingredient(s)

Benzalkonium Chloride 0.28%

Purpose

Effective Against∏

- *Staphylococcus aureus *Pseudomonas aeruginosa *E.coil
- *Salmi nella choleraesuis *Proteus vulgaris

Use

Avoid contamination of food. Avoid direct contact with eyes as may cause eye irritation, In case of direct eye contact, immediately flush eyes with plenty of water for atleast 15 minutes. If irritation persists seek medical attention.

Warnings

- 1. Unscrew lid from dispenser and remove foil seal from top.
- 2. Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3. Replace lid back and open dispensing cap.
- 4. Pull towelettes out through the dispensing eye for disinfecting use.
- 5. Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Do not use

Do not mix with other detergents or disinfectant solutions.

- 1.Unscrew lid from dispenser and remove foil seal from top.
- 2. Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3. Replace lid back and open dispensing cap.
- 4. Pull towelettes out through the dispensing eye for disinfecting use.
- 5. Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Directions

Instructions for use□

- 1.Unscrew lid from dispenser and remove foil seal from top.
- 2. Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3. Replace lid back and open dispensing cap.
- 4. Pull towelettes out through the dispensing eye for disinfecting use.
- 5. Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Other information

/

Inactive ingredients

Isopropyl Alcohol 18% Phenoxyethanol 0.3% Propylene glycol 0.3% Pure Water

Package Label - Principal Display Panel

80593-008-01 180 solution in 1 Bag



Disinfecting WipesStore below 25°C

Contains Benzalkonium chloride 0.28% v/v Isopropyl alcohol 18% v/v Inert ingredient 81.72% v/v

180pcs Towelette Size:15.2X23.2cm

Precautions:

Avoid contamination of food. Avoid direct contact with eyes as may cause eye irritation, In case of direct eye contact, immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists seek medical attention.

Effective Against:

- *Staphylococcus aureus*Pseudomonas aeruginosa*E.coil
- *Salminella choleraesuis*Proteus vulgaris

Instructions for use:

- 1. Unscrew lid from dispenser and remove foil seal from top.
- Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3. Replace lid back and open dispensing cap.
- 4.Pull towelettes out through the dispensing eye for disinfecting use.
- Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Imported & Exclusively Distributed by:
Origin Dental Pty Ltd
Suite 204/70 Caatlereagh St Sydney NSW 2000
(02)9414 7658 | supply@origindental.com.au



Disinfecting WipesStore below 25°C

Contains Benzalkonium chloride 0.28% v/v Isopropyl alcohol 18% v/v Inert ingredient 81.72% v/v

220pcs Towelette Size:15.2X23.2cm

Precautions:

Avoid contamination of food. Avoid direct contact with eyes as may cause eye irritation, In case of direct eye contact, immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists seek medical attention.

Effective Against:

- *Staphylococcus aureus*Pseudomonas aeruginosa*E.coil
- *Salminella choleraesuis*Proteus vulgaris

Instructions for use:

- 1. Unscrew lid from dispenser and remove foil seal from top.
- Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3. Replace lid back and open dispensing cap.
- 4.Pull towelettes out through the dispensing eye for disinfecting use.
- Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Imported & Exclusively Distributed by:
Origin Dental Pty Ltd
Suite 204/70 Caatlereagh St Sydney NSW 2000
(02)9414 7658 | supply@origindental.com.au

80593-008-03 80 solution in 1 canister

Avoid contamination of food. Avoid direct contact with eyes as may cause eye irritation, In case of direct eye contact, immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists seek medical attention.

Effective Against:

- *Staphylococcus aureus*Pseudomonas aeruginosa*E.coil
- *Salminella choleraesuis*Proteus vulgaris



Disinfecting Wipes

Store below 25°C

Contains Benzalkonium chloride 0.28% v/v Isopropyl alcohol 18% v/v Inert ingredient 81.72% v/v

80pcs Towelette Size:15.2X23.2cm

Instructions for use:

- 1.Unscrew lid from dispenser and remove foil seal from top.
- Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3.Replace lid back and open dispensing cap.
- 4.Pull towelettes out through the dispensing eye for disinfecting use.
- Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Imported & Exclusively Distributed by:
Origin Dental Pty Ltd
Suite 204/70 Caatlereagh St Sydney NSW 2000
(02)9414 7658 | supply@origindental.com.au

80593-008-04 100 solution in 1 canister

Precautions:

Avoid contamination of food. Avoid direct contact with eyes as may cause eye irritation, In case of direct eye contact, immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists seek medical attention.

Effective Against:

- *Staphylococcus aureus*Pseudomonas aeruginosa*E.coil
- *Salminella choleraesuis*Proteus vulgaris



ORIGIN DENTAL

Disinfecting Wipes

Store below 25°C

Contains Benzalkonium chloride 0.28% v/v Isopropyl alcohol 18% v/v Inert ingredient 81.72% v/v 100pcs

Towelette Size:15.2X23.2cm

Instructions for use:

- 1.Unscrew lid from dispenser and remove foil seal from top.
- Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3. Replace lid back and open dispensing cap.
- Pull towelettes out through the dispensing eye for disinfecting use.
- 5.Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Imported & Exclusively Distributed by:
Origin Dental Pty Ltd
Suite 204/70 Caatlereagh St Sydney NSW 2000
(02)9414 7658 | supply@origindental.com.au

80593-008-05 160 solution in 1 canister

Precautions

Avoid contamination of food. Avoid direct contact with eyes as may cause eye irritation, In case of direct eye contact, immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists seek medical attention.

Effective Against:

- $*Staphylococcus \ aureus*Pseudomonas \ aeruginosa*E.coil$
- $*Salminella\ choleraesuis*Proteus\ vulgaris$



Disinfecting Wipes

Store below 25°C

Contains Benzalkonium chloride 0.28% v/v Isopropyl alcohol 18% v/v Inert ingredient 81.72% v/v

160pcs Towelette Size:15.2X23.2cm

Instructions for use:

- $1. Unscrew\ lid\ from\ dispenser\ and\ remove\ foil\ seal\ from\ top.$
- 2. Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3.Replace lid back and open dispensing cap.
- 4.Pull towelettes out through the dispensing eye for disinfecting use.
- Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Imported & Exclusively Distributed by:
Origin Dental Pty Ltd
Suite 204/70 Caatlereagh St Sydney NSW 2000
(02)9414 7658 | supply@origindental.com.au

80593-008-06 180 solution in 1 canister

Avoid contamination of food. Avoid direct contact with eyes as may cause eye irritation, In case of direct eye contact, immediately flush eyes with plenty of water for at least 15 minutes.If irritation persists seek medical attention.

Effective Against:

- *Staphylococcus aureus*Pseudomonas aeruginosa*E.coil
- *Salminella choleraesuis*Proteus vulgaris



Disinfecting Wipes

Store below 25°C

Contains Benzalkonium chloride 0.28% v/v Isopropyl alcohol 18% v/v Inert ingredient 81.72% v/v

Towelette Size:15.2X23.2cm

Instructions for use:

- 1. Unscrew lid from dispenser and remove foil seal from top.
- 2. Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3.Replace lid back and open dispensing cap.
- 4.Pull towelettes out through the dispensing eye for disinfecting
- 5.Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Imported & Exclusively Distributed by: Origin Dental Pty Ltd Suite 204/70 Caatlereagh St Sydney NSW 2000 (02)9414 7658 | supply@origindental.com.au

80593-008-07 220 solution in 1 canister

Precautions:

Avoid contamination of food. Avoid direct contact with eves as may cause eye irritation, In case of direct eye contact, immediately flush eyes with plenty of water for at least 15 minutes.If irritation persists seek medical attention.

Effective Against:

- *Staphylococcus aureus*Pseudomonas aeruginosa*E.coil
- *Salminella choleraesuis*Proteus vulgaris



ORIGIN DENTAL

Disinfecting Wipes

Store below 25°C

Contains Benzalkonium chloride 0.28% v/v Isopropyl alcohol 18% v/v Inert ingredient 81.72% v/v 220pcs Towelette Size:15.2X23.2cm

Instructions for use:

- 1. Unscrew lid from dispenser and remove foil seal from top.
- 2. Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3.Replace lid back and open dispensing cap.
- 4.Pull towelettes out through the dispensing eye for disinfecting
- 5. Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Imported & Exclusively Distributed by: Origin Dental Pty Ltd Suite 204/70 Caatlereagh St Sydney NSW 2000 (02)9414 7658 | supply@origindental.com.au

Avoid contamination of food. Avoid direct contact with eyes as may cause eye irritation, In case of direct eye contact, immediately flush eyes with plenty of water for at least 15 minutes.If irritation persists seek medical attention.

Effective Against:

- *Staphylococcus aureus*Pseudomonas aeruginosa*E.coil
- *Salminella choleraesuis*Proteus vulgaris



Disinfecting Wipes

Store below 25°C

Contains Benzalkonium chloride 0.28% v/v Isopropyl alcohol 18% v/v Inert ingredient 81.72% v/v

Towelette Size:15.2X23.2cm

Instructions for use:

- 1.Unscrew lid from dispenser and remove foil seal from top.
- 2. Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3.Replace lid back and open dispensing cap.
- 4.Pull towelettes out through the dispensing eye for disinfecting
- 5.Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Imported & Exclusively Distributed by: Origin Dental Pty Ltd Suite 204/70 Caatlereagh St Sydney NSW 2000 (02)9414 7658 | supply@origindental.com.au

Avoid contamination of food. Avoid direct contact with eyes as may cause eye irritation, In case of direct eye contact, immediately flush eyes with plenty of water for at least 15 minutes.If irritation persists seek medical attention.

Effective Against:

- *Staphylococcus aureus*Pseudomonas aeruginosa*E.coil
- *Salminella choleraesuis*Proteus vulgaris

Instructions for use:

- 1.Unscrew lid from dispenser and remove foil seal from top.
- 2. Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3.Replace lid back and open dispensing cap.
- 4.Pull towelettes out through the dispensing eye for disinfecting
- 5. Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Imported & Exclusively Distributed by: Origin Dental Pty Ltd Suite 204/70 Caatlereagh St Sydney NSW 2000 (02)9414 7658 | supply@origindental.com.au



Disinfecting Wipes

Store below 25°C

Contains Benzalkonium chloride 0.28% v/v Isopropyl alcohol 18% v/v Inert ingredient 81.72% v/v

500pcs

Towelette Size: 15.2X23.2cm

80593-008-10 800 solution in 1 canister

Avoid contamination of food. Avoid direct contact with eyes as may cause eye irritation, In case of direct eye contact, immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists seek medical attention.

Effective Against:

- *Staphylococcus aureus*Pseudomonas aeruginosa*E.coil
- *Salminella choleraesuis*Proteus vulgaris

Instructions for use:

- 1.Unscrew lid from dispenser and remove foil seal from top.
- 2. Take first towelette from centre of roll and place through the dispensing eye on lid.
- 3.Replace lid back and open dispensing cap.
- 4.Pull towelettes out through the dispensing eye for disinfecting
- 5. Close dispensing cap after each use to avoid evaporation of product liquid.
- 6.Do not mix with other detergents or disinfectant solutions.

Imported & Exclusively Distributed by: Origin Dental Pty Ltd Suite 204/70 Caatlereagh St Sydney NSW 2000 (02)9414 7658 | supply@origindental.com.au



Disinfecting Wipes

Store below 25°C

Contains

Benzalkonium chloride 0.28% v/v Isopropyl alcohol 18% v/v Inert ingredient 81.72% v/v

800pcs

Towelette Size: 15.2X23.2cm

ANTIBACTERIAL WIPES UNSCENTED

benzethonium chloride solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80593-008	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM -BENZ ALKONIUM 0.28 g UNII:7N6JUD5X6Y) **CHLORIDE** in 100

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80593-008- 01	180 in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:80593-008- 03	80 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
3	NDC:80593-008- 09	500 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
4	NDC:80593-008- 04	100 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
5	NDC:80593-008- 02	220 in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
6	NDC:80593-008- 05	160 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
7	NDC:80593-008- 06	180 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
8	NDC:80593-008- 07	220 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
9	NDC:80593-008- 10	800 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
10	NDC:80593-008- 08	300 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

Labeler - ZHANGZHOU WANSIKE ELECTRONICS CO., LTD (560452758)

Establishment				
Name	Address	ID/FEI	Business Operations	
ZHANGZHOU WANSIKE ELECTRONICS CO., LTD		560452758	manufacture(80593-008)	

Revised: 3/2021 ZHANGZHOU WANSIKE ELECTRONICS CO., LTD