DUROKLEEN SANITIZING WIPE- benzalkonium chloride cloth NuGenTec

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.

DuroKleen Sanitizing Wipe

Active Ingredient(s)

Benzalkonium Chloride 0.10%

Purpose

Antiseptic, Hand Sanitizer, Antibacterial

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash 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.

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Directions

- Rub cloth product on hands to cover and wet all surfaces. Allow to dry without wiping
- Supervise children under 6 years of age when using this product to avoid swallowing.

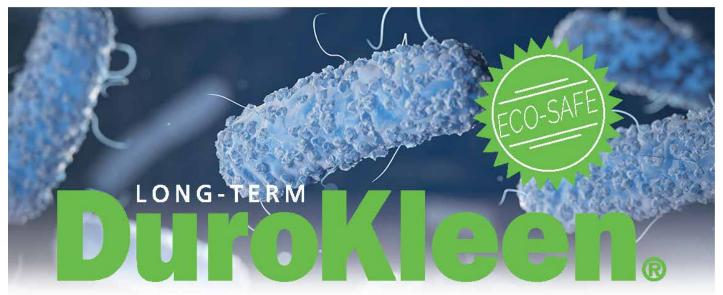
Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

hydrogen peroxide, Ztrex 72 MUP, purified water USP, non-woven cloth

Package Label - Principal Display Panel



Hospital Grade Wipe Disinfectant



No Volatile Organic Compounds

No Harsh Chemicals

Won't Stain or Burn

Long-term Protection

Eliminates Odor

Controls 99.9% of Microbes

Long-term DuroKleen provides a long-lasting invisible biostatic barrier that prevents the growth of molds, mildew, fungus, algae, bacteria and viruses on

skin and soft surfaces.

Highly effective as a durable surface protection for the long-term elimination and control of a wide spectrum of microbial life forms, including fungi that produce communicable infections or appear as mold or mildew, and bacteria that may cause disease, odor and discoloration.

FOR USER AND SAFETY INSTRUCTIONS, REFER TO THE LABEL ON REVERSE SIDE OF CONTAINER

Benzalkonium chloride0.1% %w/v | Hydrogen peroxide0.2% %w/v



PRODUCED FOR: Durokleen Global Pty Ltd ACN 630 884 105 Suite 401, 55 Plaza Parade, Maroochydore QLD 4558 Australia. Ph 1300 911 695 www.durokleen.com

NET CONTENTS 100 Wet Wipes



DIRECTIONS FOR USE

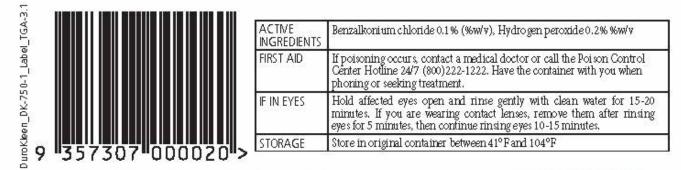
FOR SKIN SURFACE PROTECTION: DuroKleen Wipes are formulated ready for use. Open Can and pull out wipe, rub thoroughly all over hand making sure the surface is completely covered. Let stand until dry.

NET CONTENTS 100 Wet Wipes

CAUTION: Avoid contact with eyes; may cause moderate eye irritation. Do Not Ingest. Do not use as baby wipe or for personal cleaning.

Manufactured by: NuGenTec 1155 Park Avenue, Emeryville, CA 94608 Made in the USA

FDA NDC Code: 77368-911-10



Durokleen Global Pty Ltd, 401 / 55 Plaza Pde, Maroochydore QLD 4558 Australia. Ph 1300 911 695 www.durokleen.com

100 count in one canister NDC: 77368-911-10

| DUROKLEEN SANITIZING WIPE benzalkonium chloride cloth | | | | | | | | | | |
|--|----------------|--------------------|---------------|--|--|--|--|--|--|--|
| Product Information | | | | | | | | | | |
| Product Type Route of Administration | HUMAN OTC DRUG | Item Code (Source) | NDC:77368-912 | | | | | | | |
| Route of Administration | TOPICAL | | | | | | | | | |
| | | | | | | | | | | |
| Active Ingredient/Active Moiety | | | | | | | | | | |

| | | | Ingredient Name | Basis of Streng | gth | Strength |
|--|---|---------------------------------------|---|---------------------------------|---------------------|-----------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6 JUD5X6 Y) | | | BENZALKONIUM CHLORIDE | | 0.1 mg in 100 mL | |
| | | | | | | |
| In | active Ingredie | ents | | | | |
| | | | Ingredient Name | | | Strength |
| DI | METHYLTETRADE | ECYL | (3-(TRIMETHO XYSILYL)PROPYL)AMMONIUM CH | HLORIDE (UNII: N7BH1NT) | V97) | 0.2 mL in 100 m |
| HY | DROGEN PEROXI | DE (l | JNII: BBX060AN9V) | | | 0.2 mL in 100 m |
| WATER (UNII: 059QF0KO0R) | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| Pa | ickaging | | | | | |
| Pa # | ickaging Item Code | | Package Description | Marketing Start Date | Mark | keting End Dat |
| # | | 100 | 5 K | Marketing Start Date 03/30/2020 | Mark | keting End Dat |
| # | Item Code | | 5 K | 03/30/2020 | Mark | keting End Dat |
| # 1 1 1 1 | Item Code | 245 | in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product | 03/30/2020 | Mark | keting End Dat |
| # 1 1 1 1 | Item Code NDC:77368-912-10 | 245 200 | in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product | 03/30/2020 | Mark | keting End Dat |
| # 1 1 1 2 1 2 1 | Item Code NDC:77368-912-10 | 245 200 490 | in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product | 03/30/2020 | Mark | keting End Dat |
| # 1 1 1 2 1 2 1 | Item Code NDC:77368-912-10 NDC:77368-912-20 | 245 1 200 490 70 ir | in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product | 03/30/2020 | Mark | keting End Dat |
| # 1 1 2 3 | Item Code NDC:77368-912-10 NDC:77368-912-20 | 245 1 200 490 70 ir | in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product a 1 PACKAGE | 03/30/2020 | Mark | keting End Dat |
| # 1 1 2 3 | Item Code NDC:77368-912-10 NDC:77368-912-20 | 245 1 200 490 70 ir | in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product a 1 PACKAGE | 03/30/2020 | Mark | xeting End Dat |
| # 1 1 2 2 3 3 | Item Code NDC:77368-912-10 NDC:77368-912-20 NDC:77368-912-07 | 245 1 200 490 70 ir 172 1 | in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product a 1 PACKAGE nL in 1 PACKAGE; Type 0: Not a Combination Product | 03/30/2020 | Mark | keting End Dat |
| # 1 1 2 2 3 3 | Item Code NDC:77368-912-10 NDC:77368-912-20 | 245 1 200 490 70 ir 172 1 | in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product a 1 PACKAGE nL in 1 PACKAGE; Type 0: Not a Combination Product | 03/30/2020 | Mark | keting End Dat |
| # 1 1 2 1 2 3 3 | Item Code NDC:77368-912-10 NDC:77368-912-20 NDC:77368-912-07 | 245 1 200 490 70 ir 172 1 | in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product in 1 CANISTER mL in 1 PACKAGE; Type 0: Not a Combination Product a 1 PACKAGE nL in 1 PACKAGE; Type 0: Not a Combination Product | 03/30/2020 | | keting End Dat |

Labeler - NuGenTec (090331927)

Registrant - NuGenTec (090331927)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------|---------|-----------|------------------------|
| NuGenTec | | 090331927 | manufacture(77368-912) |

Revised: 1/2021

NuGenTec