

OKAY WOMENS ALUMINIUM FREE DEODORANT STICK- aluminum zirconium tetrachlorohydrate gly stick Xtreme Tools International, 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.

Active Ingredient

Aluminum Zirconium Tetrachlorohydrate GLY (20%).....Purpose: Antiperspirant

Purpose

Antiperspirant

Uses

Reduces underarm wetness.

Warnings

For external use only.

Do not use on broken skin.

Stop Use and ask doctor if Rash or irritation occurs.

Ask a doctor before use if you have kidney disease.

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

Directions

Apply to underarms only.

Inactive Ingredients

Cyclopentasiloxane, Cetearyl Alcohol, PPG-14-Butyl Ether, Hydroxypropyl Starch Phosphate, Propylene Glycol, Glyceryl Stearate, PEG-100 Stearate, Myristyl Myristate,

Silica Dimethyl Silylate, Cetyl Ricinoleate, PEG-40-Hydrogenated Castor Oil, Fragrance.

Questions or comments?

Call 1-305-622-7474 Monday-Friday 9:00 AM to 5:00 PM

Package Label

56 gr (2oz) in Twist up Tube (NDC 74553-008-01)

| Drug Facts | |
|--|----------------------------------|
| Active Ingredient Aluminum Zirconium Tetrachlorohydrax GLY (20%) | Purpose Antiperspirant |
| Uses Reduces underarm wetness | |
| Warning For external use only. Do not use on broken skin. | |
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Package Label

85 gr (3oz) in Twist up Tube (NDC 74553-008-02)

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OKAY-DEOWS3 OK026999

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AI

Aluminum Free

D

Dry Protection

F

Fresh Scent

D

Daily Protection

Pure Naturals®

WOMEN'S

Aluminium Free Deodorant Stick
 Stick déodorant sans aluminium

Natural Fresh

Daily Odor Protection

Net Wt. 3 oz / 85gr

DITOS

Drug Facts

| | |
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AI

Aluminum Free

D

Dry Protection

F

Fresh Scent

D

Daily Protection

Pure Naturals®

WOMEN'S

Aluminium Free Deodorant Stick
 Stick déodorant sans aluminium

Natural Fresh

Daily Odor Protection

Net Wt. 3 oz / 85gr

DITOS

Drug Facts

| | |
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OKAY WOMENS ALUMINIUM FREE DEODORANT STICK

aluminum zirconium tetrachlorohydrate gly stick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74553-008 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|------------------|
| ALUMINUM ZIRCONIUM TETRACHLOROXYDREX GLY (UNII: 80386558JE) (ALUMINUM ZIRCONIUM TETRACHLOROXYDREX GLY - UNII:80386558JE) | ALUMINUM ZIRCONIUM TETRACHLOROXYDREX GLY | 20 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| PPG-14 BUTYL ETHER (UNII: R199TJT95T) | |
| HYDROXYPROPYL DISTARCH PHOSPHATE, HIGH AMYLOSE CORN (UNII: 9F8ET54T05) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

| | |
|---|--|
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| MYRISTYL MYRISTATE (UNII: 4042ZC00DY) | |
| SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W) | |
| CETYL RICINOLEATE (UNII: 1P677500YD) | |
| POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:74553-008-01 | 56 g in 1 TUBE; Type 0: Not a Combination Product | 05/14/2021 | |
| 2 | NDC:74553-008-02 | 85 g in 1 TUBE; Type 0: Not a Combination Product | 05/14/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part350 | 05/14/2021 | |

Labeler - Xtreme Tools International, Inc (125398904)

Registrant - Xtreme Tools International, Inc (125398904)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------|---------|-----------|------------------------|
| Xtreme Tools International, Inc | | 125398904 | manufacture(74553-008) |

Revised: 5/2021

Xtreme Tools International, Inc