UTRASURE- otc antiprespirant drug product spray DermaRite Industries LLC

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.

DRUG LISTING:ULTRASURE SPRAY

Active Ingredient

Aluminum Sesquichlorohydrate 15%

Purpose:

Anti-perspirant

Uses:

- Reduce underarm wetness
- 24 hour protection

Warnings:

- For external use only.
- Do not use on broken skin.
- **Avoid contact with eyes.** In case of contact, flush thoroughly with water.
- Stop use and ask doctor if you have Kidney Disease.

Warnings:

• **Keep out of reach of children.** If swallowed, contact physician or Poison Control Center right away.

Directions:

- Apply to under arms only.
- Hold in an upright position about 6 inches from the underarm and spray.

Other Information

- Store at room temperature (59°-86°F).
- You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047

Inactive Ingredients:

Fragrance, PEG-40 Castor Oil, Propylene Glycol, SD Alcohol 40-B, Water

Questions?

Call 1-800-337-6296 Mon-Fri 9AM-5PM EST.

Package Label Principal Display Panel



Drug Facts

Active ingredient

Purpose Anti-perspirant

Aluminum Sesquichlorohydrate 15%

Uses ■ Reduces underarm wetness ■ 24 hour protection

For external use only.

Do not use on broken skin.

Avoid contact with eyes. In case of contact, flush thoroughly with

Stop use and ask a doctor if rash or irritation develops.

Ask a doctor before use If you have Kidney Disease.

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

Directions ■ Apply to underarms only. ■ Hold in an upright position about 6 inches from underarms and spray.

Other information Store at room temperature (59'-86' F). ■ You may report a serious adverse event to DermaRite Industries. PO Box 7209, North Bergen, NJ 07047.

Inactive ingredients Water, SD Alcohol 40-B, PEG-40 Castor Oil, Propylene Glycol, Fragrance

Questions? Call 1-800-337-6296 Mon - Fri 9AM - 5PM EST.



DermaRite Industries LLC • 7777 West Side Avenue North Bergen, NJ 07047 . www.dermarlte.com

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UTRASURE

otc antiprespirant drug product spray

Product Information

Product Type HUMAN OTC DRUG NDC:61924-266 Item Code (Source)

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength ALUMINUM SESQUICHLOROHYDRATE (UNII: UCN889409V) (ALUMINUM ALUMINUM 0.15 g SESQUICHLOROHYDRATE - UNII:UCN889409V) SESQUICHLOROHYDRATE in 100 mL

Inactive Ingredients

Ingredient Name	Strength			
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
ALCOHOL (UNII: 3K9958V90M)				
WATER (UNII: 059QF0KO0R)				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:61924-266- 04	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/24/2010		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part350	02/24/2010				

Labeler - DermaRite Industries LLC (883925562)

Establishment						
Name	Address	ID/FEI	Business Operations			
DermaRite Industries LLC		883925562	api manufacture(61924-266)			

Revised: 1/2020 DermaRite Industries LLC