

ANTIPERSPIRANT DEODORANT - aluminum chlorohydrate liquid

Frabel S.A de C.V.

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 Facts

Active Ingredient

Aluminum chlorohydrate 15%

Purpose

Antiperspirant

Uses

Reduces underarm perspiration

Warnings

For external use only

Do not use on broken skin.

Stop use if rash or irritation occurs.

Ask a doctor before use if you have kidney disease

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

Apply to underarms only

Drug Facts (continued) Inactive Ingredients

water, corn starch, cetearyl alcohol, fragrance, dimethicone, linalool, alpha-isomethyl ionone, geraniol, cetareth-33, butylphenyl methylpropional, citronellol

Package Label

Package Label

OBAO

Delicate skin

24hrs

ANTIPERSPIRANT

With natural active absorbent

2.2 FL OZ (65 mL)

PEEL BACK FOR MORE DRUG FACTS

| Drug Facts | |
|--|----------------|
| Active Ingredient | Purpose |
| Aluminum Chlorohydrate 15%... | Antiperspirant |
| Uses Reduces underarm perspiration | |
| Warnings | |
| For external use only | |
| Do not use on broken skin | |
| Stop use if rash or irritation occurs | |
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| Keep out of the reach of children if swallowed, get medical help or contact a Poison Control Center right away | |
| Directions Apply to underarms only | |

FRABEL S.A. DE C.V. PRODUCT OF MEXICO
Oklahoma No. 14 Col.
Nápoles C.P. 63810 México D.F.

LOT NO.
EXP. DATE
8 85751 00000 2

Drug Facts (continued)

Inactive Ingredients water, corn starch, cetearyl alcohol, fragrance, dimethicone, linalool, alpha-isomethyl ionone, geraniol, ceteareth-33, butylphenyl methylpropional, citronellol.

ANTIPERSPIRANT DEODORANT

aluminum chlorohydrate liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50636-003 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|------------------------|--------------------|
| ALUMINUM CHLOROHYDRATE (UNII: HPN8MZW13M) (ALUMINUM CATION - UNII:3XHB1D032B) | ALUMINUM CHLOROHYDRATE | 15 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| LINALOOL, DL- (UNII: D81QY6I88E) | |
| GERANIOL (UNII: L837108USY) | |
| CITRONELLOL, DL- (UNII: 565OK72VNF) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------------|----------------------|--------------------|
| 1 | NDC:50636-003-65 | 65 mL in 1 BOTTLE, WITH APPLICATOR | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part350 | 03/31/2010 | |

Labeler - Frabel S.A de C.V. (810323162)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|---------------------|
| Frabel S.A de C.V. | | 810323162 | manufacture |