

GINGI-AID SOLUTION- aluminum chloride 25% solution

Gingi-Pak a Division of the Belport

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.

Gingi-Aid Solution

Active ingredient

Active ingredient

25% Aluminum Chloride w/w.

Warnings

Warnings For topical applications only. |

Precautions

PRECAUTIONS Discontinue use if irritation appears. FOR TOPICAL APPLICATION ONLY. Avoid eye contact.

Purpose

Purpose

Hemostyptic

Storage

Avoid excessive heat
above 40 °C (104 °F).

Uses

Uses For the control of bleeding or topical hemostasis in routine dental procedures including: implantation, root canals, gingivectomy, frenectomy, tissue retraction, oral surgery, and crown and bridge preparations.

Description

DESCRIPTION Gingi-Aid® is a topical astringent solution of Aluminum Chloride ($\text{AlCl}_3 \cdot 6\text{H}_2\text{O}$). Gingival retraction is achieved using a plain gingival retraction cord moistened with Gingi-Aid Solution.

Contraindications

CONTRAINDICATIONS In patients with a known history of hypersensitivity to aluminum chloride.

Keep out of reach of children

KEEP OUT OF REACH OF CHILDREN.



Direction

Gingi-Aid solution should be used at room temperature with cotton pellets, sponge or syringe with tips. It can be soaked into an un-medicated retraction cord or braid with is then packed into the gingival.

Inactive ingredients

Inactive ingredients: Purified water, Chlorobutanol

Principal display

| | |
|---|---|
| GINGI-AID [®] R_x only ← OPEN HERE | |
| 25% Buffered Aluminum Chloride Topical Hemostatic Solution REF 12114 | Epinephrine-Free Contains: Aluminum Chloride-6-Hydrate 25% in an aqueous vehicle with buffering agents. EN - Aluminum Chloride Solution DE - Aluminiumchlorid Lösung FR - Solution de Chlorure d'Aluminium NL - Aluminiumchlorid Solution IT - Cloruro d'Alluminio Soluzione ES - Cloruro de Aluminio Solución PT - Solução de Cloreto de Alumínio SV - Aluminiumklorid Lösning DA - Aluminiumchloride Solution FI - Alumiinikloridi Ratkaisu EL - Χλωριούχο αργίλιο Λύση Caution: Federal law restricts this product to sale or use on the order of a dentist. Avoid excessive heat above 40 °C (104 °F). GINGI-PAK Manufactured by: Gingi-Pak 4825 Calle Alto Camarillo, CA 93011 USA www.gingi-pak.com  |
| 15cc | Made in USA |
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| 40cc | Made in USA |

GINGI-AID SOLUTION

aluminum chloride 25% solution

Product Information

| | | | |
|--------------------------------|--|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10 129-017 |
| Route of Administration | DENTAL, ORAL, PERIODONTAL, SUBGINGIVAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| ALUMINUM CHLORIDE (UNII: 3CYT62D3GA) (ALUMINUM CATION - UNII:3XHB1D032B) | ALUMINUM CHLORIDE | 3.75 g in 15 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------|-----------------|
| CHLOROBUTANOL (UNII: HM4YQM8WRC) | 3 mg in 15 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|-------------------|---|-----------------------------|---------------------------|
| 1 | NDC:10 129-017-02 | 15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/04/1990 | |
| 2 | NDC:10 129-017-03 | 40 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/04/1990 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final | part350 | 04/04/1990 | |

Labeler - Gingi-Pak a Division of the Belport (008480121)

Revised: 2/2018

Gingi-Pak a Division of the Belport