

GINGI-AID MAX Z-TWIST 1- gingi-aid max z-twist 1 solution
GINGI-AID MAX Z-TWIST 00- gingi-aid max z-twist 00 solution
GINGI-AID MAX Z-TWIST 3- gingi-aid max z-twist 3 solution
GINGI-AID MAX Z-TWIST 2- gingi-aid max z-twist 2 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 MAX Z-Twist

Active ingredients

Active Ingredient

Aluminum Sulfate 0.197 mg/cm

Precautions

Precautions Read and follow all instructions; for professional in-office use only. →

Warnings

Warnings For topical use only, do not ingest. Keep out of reach of children. Not for use on pregnant or nursing women.

Contraindications

Contraindication In individuals with **CARDIOVASCULAR DISEASE, DIABETES, HYPERTHYROIDISM, HYPERTENSION, ARTERIOSCLEROSIS AND/OR TREATED WITH TRICYCLIC ANTIDEPRESSANTS. SYSTEMIC REACTIONS IS INTENSIFIED BY INHALATION OF ANESTHETICS CONTAINING HALOGEN OR CYCLOPENTANE.**

Purpose

Purpose

Gingival Retraction

Keep out of reach of children

Warnings For topical use only, do not ingest. Keep out of reach of children. Not for use on pregnant or nursing women.

Indication and Uses

Indications for use Gingival retraction cord is intended to be used for the temporary retraction and hemostasis of the gingival margin during dental procedures. For use of the device during dental procedures such as but not limited to:

Dental impressions, Seating of temporary and permanent restorations, Restorations of cavities and replacement of a rubber dam.

Uses Gingi-AID® MAX Z-TWIST® is braided soft, absorbent cotton cord impregnated with a solution of aluminum sulfate. The gingival retraction cord is primarily used to push the gum tissue away from the prepared margins of the tooth, in order to create an accurate impression of the teeth. All retraction cords are braided to prevent fraying and penetration of the instrument through the cord while packaging.

Avoid excessive heat

Avoid Excessive heat Above 40 °C (104 °F).

Directions for use

Directions for use

1. Evaluate the health status of the gingiva and the depth of the sulcus. Use a cord large enough to firmly compress into sulcus.
2. Twist the first cord and loop it around the preparation.
3. Twist the second cord tightly and repeat the process.
4. Gingi-AID® completely retracts tissue with five to eight minutes and should then be removed from the mouth.
5. Once the cord is removed, the retraction is maintained for 30 seconds. Dispensed portions of cord are intended for single use only and should be disposed of immediately after use.

Contents

Contents Each bottle contains 108 inches braided cotton cord. The average concentration of aluminum sulfate for each size is: 0.5 mg. Per inch / 0.197 mg per cm of Z-Twist®.

Gingi-Aid Max Z-twist 00

GINGI-AID[®] MAX **R_x only** ◀ OPEN HERE

00 **Z-TWIST[®]**
Braided Gingival Retraction Cord with Aluminum Sulfate



Braided

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 93012 USA
www.gingi-pak.com

Contains 108" (274 cm) braided cotton cord impregnated with an average concentration of 0.5 mg/in (0.197 mg/cm) Aluminum Sulfate.

Made in USA

59°F 86°F

NDC 10129-059-01
REF 12170M

Gingi-Aid Max Z-twist 1

GINGI-AID[®] MAX **R_x only** ◀ OPEN HERE

1 **Z-TWIST[®]**
Braided Gingival Retraction Cord with Aluminum Sulfate



Braided

Caution: Federal law restricts this product to sale or use on the order of a dentist. Avoid excessive heat above 40 °C (104 °F).

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Made in USA

59°F 86°F

NDC 10129-060-01
REF 12171

Gingi-Aid Max Z-twist 2

GINGI-AID[®] MAX **R_x only** ◀ OPEN HERE

2 **Z-TWIST[®]**
Braided Gingival Retraction Cord with Aluminum Sulfate



Braided

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 93012 USA
www.gingi-pak.com

Contains 108" (274 cm) braided cotton cord impregnated with an average concentration of 0.5 mg/in (0.197 mg/cm) Aluminum Sulfate.

Made in USA

59°F 86°F

NDC 10129-061-01
REF 12172M

Gingi-Aid Max Z-twist 3



GINGI-AID MAX Z-TWIST 1

gingi-aid max z-twist 1 solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-060
Route of Administration	DENTAL, PERIODONTAL, SUBGINGIVAL, ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM SULFATE (UNII: 34S289N54E) (ALUMINUM SULFATE ANHYDROUS - UNII:I7T908772F)	ALUMINUM SULFATE	54 mg

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	2740 mm

Product Characteristics

Color	blue (Teal)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 129-060-01	1 in 1 VIAL, PLASTIC; Type 0: Not a Combination Product	01/15/1995	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part347	01/13/1995	
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GINGI-AID MAX Z-TWIST 00

gingi-aid max z-twist 00 solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-059
Route of Administration	ORAL, DENTAL, PERIODONTAL, SUBGINGIVAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM SULFATE (UNII: 34S289N54E) (ALUMINUM SULFATE ANHYDROUS - UNII:I7T908772F)	ALUMINUM SULFATE	54 mg

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	2740 mm

Product Characteristics

Color	blue (Teal)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 129-059-01	1 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/15/1995	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/13/1995	

GINGI-AID MAX Z-TWIST 3

gingi-aid max z-twist 3 solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-062
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Route of Administration ORAL, DENTAL, PERIODONTAL, SUBGINGIVAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM SULFATE (UNII: 34S289N54E) (ALUMINUM SULFATE ANHYDROUS - UNII:I7T908772F)	ALUMINUM SULFATE	54 mg

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	2740 mm

Product Characteristics

Color	blue (Teal)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 129-062-03	1 in 1 VIAL, PLASTIC; Type 0: Not a Combination Product	07/31/1998	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/31/1998	

GINGI-AID MAX Z-TWIST 2

gingi-aid max z-twist 2 solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-061
Route of Administration	ORAL, DENTAL, PERIODONTAL, SUBGINGIVAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM SULFATE (UNII: 34S289N54E) (ALUMINUM SULFATE ANHYDROUS - UNII:I7T908772F)	ALUMINUM SULFATE	54 mg

Inactive Ingredients

Ingredient Name		Strength		
COTTON FIBER (UNII: 70LDW53ROO)		2740 mm		
Product Characteristics				
Color	blue (Teal)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 129-061-01	1 in 1 VIAL, PLASTIC; Type 0: Not a Combination Product	01/15/1995	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	01/13/1995		

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

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