

GINGI-PAK MAX SOFT-TWIST NO 1- dl epinephrine hci solution
GINGI-PAK MAX SOFT-TWIST NO 2- dl epinephrine hci solution
GINGI-PAK MAX Z-TWIST NO 1- dl epinephrine hci solution
GINGI-PAK MAX Z-TWIST NO 2- dl epinephrine hci solution
GINGI-PAK MAX Z-TWIST NO 3- dl epinephrine hci solution
GINGI-PAK MAX 2-PLY- dl epinephrine hci solution
GINGI-PAK MAX Z-TWIST NO 00- dl epinephrine hci solution
GINGI-PAK MAX SOFT-TWIST NO 3- dl epinephrine hci solution
CROWN-PAK MAX 4-PLY- dl epinephrine hci solution
GINGI-PAK COTTON COIL- dl epinephrine hci solution
GINGI-PAK PELLETS- dl epinephrine hci solution
Gingi-Pak a Division of the Belpo

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Gingi-Pak Retraction Cord

Active ingredient

Active Ingredient

dl-Epinephrine HCl 0.197 mg/cm

Ask a doctor

Stop use and ask a doctor if irritation appears.

Do not use

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.

Keep out of reach of children

Keep out of reach of children.

Pregnancy warning

Do not use if pregnant or nursing.

Purpose

Purpose
Gingival Retraction

Storage

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

Precautions

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

Inactive ingredient

zinc chloride, phosphoric acid, sodium hydrosulfite, sodium thiosulfate, sodium monophosphate, sodium chloride, EDTA, methylparaben, propylparaben, benzyl alcohol

Uses- Gingi-Pak Z-Twist

Gingival retraction cord is intended to be used for temporary retraction and hemostasis of 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-PAK® MAX Z-TWIST® is braided soft, absorbent cotton cord impregnated with a solution of dl-Epinephrine HCl. 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.

Direction

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-Pak® 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.

For topical use only

For topical use only. Do not ingest.

Uses- Gingi-Pak Soft-Twist

Uses Gingi-Pak® MAX SOFT-TWIST® is soft, thin, absorbent cotton cord impregnated with a solution of dl-Epinephrine HCl. 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.

Uses- Gingi-Pak 2-ply

Uses Crown-Pak® MAX 2-PLY is soft, absorbent cotton cord impregnated with a solution of dl-Epinephrine HCl. 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.

Uses- Crown-Pak 4-ply

Uses Crown-Pak® MAX 4-PLY is soft, thick, absorbent cotton cord cotton cord impregnated with a solution of dl-Epinephrine HCl. 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.

Principal display- Gingi-Pak No 00

GINGI-PAK® MAX

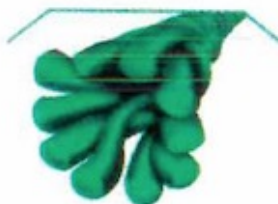
Rx only

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00

Z-TWIST®

Braided Gingival
Retraction Cord
with dl-Epinephrine HCl



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).

Contains 108" (274 cm) braided cotton cord impregnated with an average concentration of 0.5 mg/in (0.197 mg/cm) dl-Epinephrine HCl.

Made in USA

GINGI-PAK

Manufactured by: Gingi-Pak

4825 Calle Alto
Camarillo, CA 93012 USA
www.gingi-pak.com



Principal display- Gingi-Pak No 1

GINGI-PAK® MAX

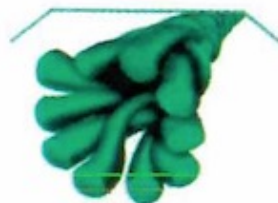
Rx only

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1

Z-TWIST®

Braided Gingival
Retraction Cord
with dl-Epinephrine HCl



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).

Contains 108" (274 cm) braided cotton cord impregnated with an average concentration of 0.5 mg/in (0.197 mg/cm) dl-Epinephrine HCl.

Made in USA

GINGI-PAK

Manufactured by: Gingi-Pak

4825 Calle Alto
Camarillo, CA 93012 USA
www.gingi-pak.com



Principal display- Gingi-Pak No 2

GINGI-PAK[®] MAX

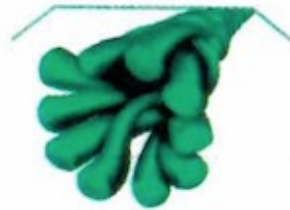
R_x only

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2

Z-TWIST[®]

Braided Gingival
Retraction Cord
with dl-Epinephrine HCl



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) dl-Epinephrine HCl.

Made in USA

Principal display- Gingi-Pak No 3

GINGI-PAK[®] MAX

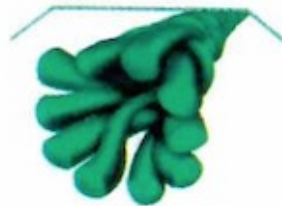
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3

Z-TWIST[®]

Braided Gingival
Retraction Cord
with dl-Epinephrine HCl



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) dl-Epinephrine HCl.

Made in USA

Principal display-Soft-Twist NO1

GINGI-PAK[®] MAX

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1

SOFT-TWIST[®]

Gingival Retraction Cord
with dl-Epinephrine HCl



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

contains 108" (274 cm) soft, very absorbent cotton cord impregnated with an average concentration of 0.5 mg/in (0.197 mg/cm) dl-Epinephrine HCl.

Made in USA

GINGI-PAK

Manufactured by: Gingi-Pak

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Principal display-Soft-Twist NO2

GINGI-PAK[®] MAX

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2

SOFT-TWIST[®]

Gingival Retraction Cord
with dl-Epinephrine HCl



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

contains 108" (274 cm) soft, very absorbent cotton cord impregnated with an average concentration of 0.5 mg/in (0.197 mg/cm) dl-Epinephrine HCl.

Made in USA

GINGI-PAK

Manufactured by: Gingi-Pak

4825 Calle Alto
Camarillo, CA 93012 USA
www.gingi-pak.com



Principal display-Soft-Twist NO3

GINGI-PAK® MAX

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3

SOFT-TWIST®

Gingival Retraction Cord
with dl-Epinephrine HCl



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

contains 108" (274 cm) soft, very absorbent cotton cord impregnated with an average concentration of 0.5 mg/in (0.197 mg/cm) dl-Epinephrine HCl.

Made in USA

GINGI-PAK

Manufactured by: Gingi-Pak

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Principal display-2-ply

GINGI-PAK® MAX

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2-PLY

Original Gingival
Retraction Cord
with dl-Epinephrine HCl



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

Contains 108" (274 cm) soft cotton cord impregnated with an average concentration of 0.5 mg/in (0.197 mg/cm) dl-Epinephrine HCl.

Made in USA

GINGI-PAK

Manufactured by: Gingi-Pak

4825 Calle Alto
Camarillo, CA 93012 USA
www.gingi-pak.com



Principal display-4-ply

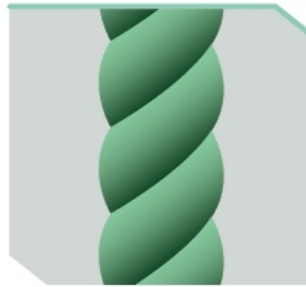
CROWN-PAK® MAX

Rx only

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4-PLY

Original Gingival
Retraction Cord
with dl-Epinephrine HCl



Contains 108" (274 cm) soft
cotton cord impregnated with an
average concentration of 0.5 mg/in
(0.197 mg/cm) dl-Epinephrine HCl.

Made in USA

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

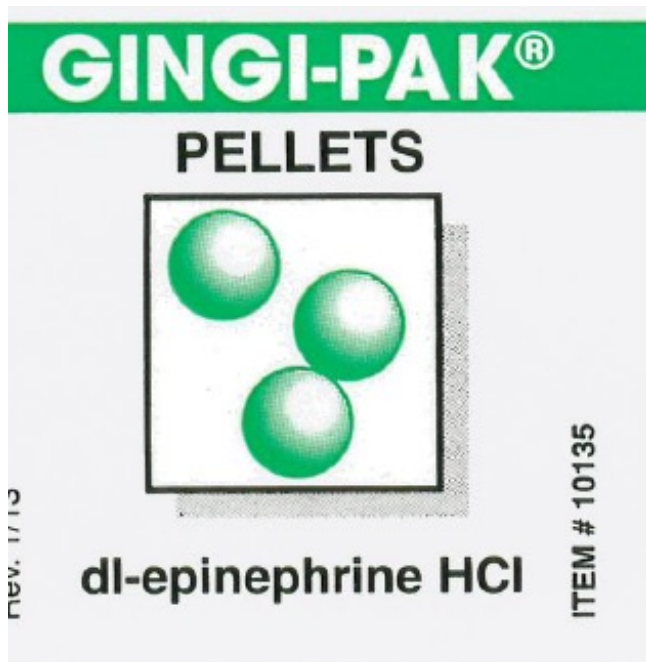
4825 Calle Alto
Camarillo, CA 93012 USA
www.gingi-pak.com



Principal display-Gingi-Pak Cotton Coil



Principal display-Gingi-Pak Pellets



GINGI-PAK MAX SOFT-TWIST NO 1

dl epinephrine hci solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-001
Route of Administration	DENTAL, SUBGINGIVAL, PERIODONTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE HYDROCHLORIDE (UNII: WBB0470O38) (EPINEPHRINE - UNII: YKH834O4BH)	EPINEPHRINE	0.197 mg in 10 mm

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	10 mm in 10 mm
SODIUM DITHIONITE (UNII: 2K5B8F6ES1)	6.15 ug in 10 mm
EDETIC ACID (UNII: 9G34HU7RV0)	0.033 ug in 10 mm
METHYL PARABEN (UNII: A2I8C7HI9T)	1.65 ug in 10 mm
PROPYL PARABEN (UNII: Z8IX2SC1OH)	0.813 ug in 10 mm
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8.13 ug in 10 mm
SODIUM THIOSULFATE (UNII: HX1032V43M)	2.46 ug in 10 mm
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	6.15 ug in 10 mm

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:10 129-001-03	2740 mm in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/1987	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/26/1987	

GINGI-PAK MAX SOFT-TWIST NO 2

dl epinephrine hci solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-002
Route of Administration	PERIODONTAL, DENTAL, SUBGINGIVAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE HYDROCHLORIDE (UNII: WBB0470O38) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	0.197 mg in 10 mm

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	10 mm in 10 mm
SODIUM DITHIONITE (UNII: 2K5B8F6ES1)	6.15 ug in 10 mm
EDETIC ACID (UNII: 9G34HU7RV0)	0.033 ug in 10 mm
METHYL PARABEN (UNII: A2I8C7HI9T)	1.65 ug in 10 mm
PROPYL PARABEN (UNII: Z8IX2SC1OH)	0.813 ug in 10 mm
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8.13 ug in 10 mm
SODIUM THIOSULFATE (UNII: HX1032V43M)	2.46 ug in 10 mm
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	6.15 ug in 10 mm

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 129-002-03	2740 mm in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/11/1985	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/11/1985	

GINGI-PAK MAX Z-TWIST NO 1

dl epinephrine hci solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-052
Route of Administration	DENTAL, SUBGINGIVAL, PERIODONTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE HYDROCHLORIDE (UNII: WBB0470O38) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	0.197 mg in 10 mm

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	10 mm in 10 mm
SODIUM DITHIONITE (UNII: 2K5B8F6ES1)	6.15 ug in 10 mm
EDETIC ACID (UNII: 9G34HU7RV0)	0.033 ug in 10 mm
SODIUM THIOSULFATE (UNII: HX1032V43M)	2.46 ug in 10 mm
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	6.15 ug in 10 mm
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8.13 ug in 10 mm
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.813 ug in 10 mm
METHYLPARABEN (UNII: A2I8C7HI9T)	1.65 ug in 10 mm

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 129-052-01	2740 mm in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/1995	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/24/1995	

GINGI-PAK MAX Z-TWIST NO 2

dl epinephrine hci solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-053
Route of Administration	DENTAL, SUBGINGIVAL, PERIODONTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE HYDROCHLORIDE (UNII: WBB0470038) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	0.197 mg in 10 mm

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	10 mm in 10 mm
SODIUM DITHIONITE (UNII: 2K5B8F6ES1)	6.15 ug in 10 mm
EDETIC ACID (UNII: 9G34HU7RV0)	0.033 ug in 10 mm
SODIUM THIOSULFATE (UNII: HX1032V43M)	2.46 ug in 10 mm
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JH2SW)	6.15 ug in 10 mm
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8.13 ug in 10 mm
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.813 ug in 10 mm
METHYLPARABEN (UNII: A2I8C7HI9T)	1.65 ug in 10 mm

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 129-053-01	2740 mm in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/1995	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/24/1995	

GINGI-PAK MAX Z-TWIST NO 3

dl epinephrine hci solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-054
Route of Administration	SUBGINGIVAL, DENTAL, PERIODONTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE HYDROCHLORIDE (UNII: WBB0470038) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	0.197 mg in 10 mm

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	10 mm in 10 mm
SODIUM DITHIONITE (UNII: 2K5B8F6ES1)	6.15 ug in 10 mm
EDETIC ACID (UNII: 9G34HU7RV0)	0.033 ug in 10 mm
SODIUM THIOSULFATE (UNII: HX1032V43M)	2.46 ug in 10 mm
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	6.15 ug in 10 mm
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8.13 ug in 10 mm
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.813 ug in 10 mm
METHYLPARABEN (UNII: A2I8C7HI9T)	1.65 ug in 10 mm

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 129-054-01	2740 mm in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/1995	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/24/1995	

GINGI-PAK MAX 2-PLY

dl epinephrine hci solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-004
Route of Administration	PERIODONTAL, DENTAL, SUBGINGIVAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE HYDROCHLORIDE (UNII: WBB047OO38) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	0.197 mg in 10 mm

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	10 mm in 10 mm
SODIUM DITHIONITE (UNII: 2K5B8F6ES1)	6.15 ug in 10 mm
EDETIC ACID (UNII: 9G34HU7RV0)	0.033 ug in 10 mm
METHYLPARABEN (UNII: A2I8C7HI9T)	1.65 ug in 10 mm
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.813 ug in 10 mm
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8.13 ug in 10 mm
SODIUM THIOSULFATE (UNII: HX1032V43M)	2.46 ug in 10 mm

SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)

6.15 ug in 10 mm

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 129-004-03	2740 mm in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/29/1984	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/29/1984	

GINGI-PAK MAX Z-TWIST NO 00

dl epinephrine hci solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-051
Route of Administration	DENTAL, SUBGINGIVAL, PERIODONTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE HYDROCHLORIDE (UNII: WBB0470O38) (EPINEPHRINE - UNII: YKH834O4BH)	EPINEPHRINE	0.197 mg in 10 mm

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	10 mm in 10 mm
SODIUM DITHIONITE (UNII: 2K5B8F6ES1)	6.15 ug in 10 mm
EDETIC ACID (UNII: 9G34HU7RV0)	0.033 ug in 10 mm
SODIUM THIOSULFATE (UNII: HX1032V43M)	2.46 ug in 10 mm
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	6.15 ug in 10 mm
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8.13 ug in 10 mm
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.813 ug in 10 mm
METHYLPARABEN (UNII: A2I8C7HI9T)	1.65 ug in 10 mm

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 129-051-01	2740 mm in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/1995	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/24/1995	

GINGI-PAK MAX SOFT-TWIST NO 3

dl epinephrine hci solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-003
Route of Administration	PERIODONTAL, DENTAL, SUBGINGIVAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE HYDROCHLORIDE (UNII: WBB0470O38) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	0.197 mg in 10 mm

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	10 mm in 10 mm
SODIUM DITHIONITE (UNII: 2K5B8F6ES1)	6.15 ug in 10 mm
EDETIC ACID (UNII: 9G34HU7RV0)	0.033 ug in 10 mm
METHYL PARABEN (UNII: A2I8C7HI9T)	1.65 ug in 10 mm
PROPYL PARABEN (UNII: Z8IX2SC1OH)	0.813 ug in 10 mm
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8.13 ug in 10 mm
SODIUM THIOSULFATE (UNII: HX1032V43M)	2.46 ug in 10 mm
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	6.15 ug in 10 mm

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 129-003-03	2740 mm in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/11/1985	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/11/1985	

CROWN-PAK MAX 4-PLY

dl epinephrine hci solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-005
Route of Administration	PERIODONTAL, DENTAL, SUBGINGIVAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE HYDROCHLORIDE (UNII: WBB0470O38) (EPINEPHRINE - UNII: YKH834O4BH)	EPINEPHRINE	0.197 mg in 10 mm

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	10 mm in 10 mm
SODIUM DITHIONITE (UNII: 2K5B8F6ES1)	6.15 ug in 10 mm
EDETIC ACID (UNII: 9G34HU7RV0)	0.033 ug in 10 mm
METHYL PARABEN (UNII: A2I8C7HI9T)	1.65 ug in 10 mm
PROPYL PARABEN (UNII: Z8IX2SC1OH)	0.813 ug in 10 mm
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8.13 ug in 10 mm
SODIUM THIOSULFATE (UNII: HX1032V43M)	2.46 ug in 10 mm
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	6.15 ug in 10 mm

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 129-005-03	2740 mm in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/29/1984	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/29/1984	

GINGI-PAK COTTON COIL

dl epinephrine hci solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-008
Route of Administration	PERIODONTAL, DENTAL, SUBGINGIVAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE HYDROCHLORIDE (UNII: WBB0470O38) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	1.18 mg in 10 mm

Inactive Ingredients

Ingredient Name	Strength
COTTON FIBER (UNII: 70LDW53ROO)	10 mm in 10 mm
SODIUM DITHIONITE (UNII: 2K5B8F6ES1)	6.15 ug in 10 mm
EDETIC ACID (UNII: 9G34HU7RV0)	0.033 ug in 10 mm
METHYL PARABEN (UNII: A2I8C7HI9T)	1.65 ug in 10 mm
PROPYL PARABEN (UNII: Z8IX2SC1OH)	0.813 ug in 10 mm
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8.13 ug in 10 mm
SODIUM THIOSULFATE (UNII: HX1032V43M)	2.46 ug in 10 mm
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	6.15 ug in 10 mm

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10129-008-01	610 mm in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/1987	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/26/1987	

GINGI-PAK PELLETS

dl epinephrine hci solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10129-007
Route of Administration	PERIODONTAL, DENTAL, SUBGINGIVAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE HYDROCHLORIDE (UNII: WBB0470O38) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	0.7 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM DITHIONITE (UNII: 2K5B8F6ES1)	2.38 ug

EDETIC ACID (UNII: 9G34HU7RV0)	0.013 ug
METHYLPARABEN (UNII: A2I8C7HI9T)	0.638 ug
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.314 ug
SODIUM CHLORIDE (UNII: 451W47IQ8X)	3.14 ug
SODIUM THIOSULFATE (UNII: HX1032V43M)	0.95 ug
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	2.38 ug

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10129-007-02	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/1987	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/26/1987	

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

Registrant - Jeff Nichols (008480121)

Establishment

Name	Address	ID/FEI	Business Operations
Gingi-Pak a Division of the Belport		008480121	manufacture(10129-051, 10129-052, 10129-053, 10129-054, 10129-001, 10129-002, 10129-003, 10129-004, 10129-005, 10129-007, 10129-008)

Revised: 12/2018

Gingi-Pak a Division of the Belport