

**STASIS- ferric sulfate solution**  
**Gingi-Pak a Division of the Belport**

*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](#).*

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**Stasis Solution**

**Active Ingredient**

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**Active ingredient**  
**21% Ferric Sulfate w/w**

**Purpose**

**Purpose**  
**Hemostyptic**

**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** STASIS® is a viscous spearmint flavored, amber-colored glycerol/aqueous solution containing 210 mg/ml Ferric Sulfate (21%).

**Actions**

**ACTIONS** STASIS® is one of the most effective and safest topical hemostyptic agents. STASIS® delivers rapid hemostasis by the formation of coagulate plugs within the capillary orifices without potential cardiovascular side effects.

**Directions**

STASIS should be used at room temperature with cotton pellets, sponge or syringe with tips. STASIS can be soaked into unmedicated retraction cord or braid which is then packed into the gingival sulcus. Remove the cord after several minutes and rinse or flush well before taking the impression. The area along with the preparation should be thoroughly dried for silicone and rubber-based impression materials. The area and the preparation should be rinsed and very wet for hydrocolloid or alginate impressions. Rapid coagulation is usually induced by the formation of a coagulate plug in the capillary. If persistent bleeding should occur, apply STASIS with pressure to the exposed capillaries using cotton tipped applicators. Scrubbing or burnishing is of questionable value and could be injurious to gingival tissue and is not recommended.

### Warning

**Warnings** For topical applications only.

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**Keep out of reach of children**

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**Stop use and ask a doctor**

**Stop use and ask a doctor if irritations or diarrhea appears.**

### Precautions

**PRECAUTIONS** Temporary discoloration of tissue may occur for 24 to 48 hours. (Reassure patient that discoloration will disappear.) IT IS NOT RECOMMENDED THAT FERRIC SULFATE SOLUTIONS SUCH AS STASIS BE USED IN COMBINATION WITH EPINEPHRINE OR EPINEPHRINE

IMPREGNATED RETRACTION MATERIALS BECAUSE LONG TERM AND POSSIBLE PERMANENT STAINING MIGHT OCCUR. Stains on hands and clothing may generally be removed with the use of 3% Hydrogen Peroxide.

### Storage

**STORAGE** STASIS® should be protected from direct sunlight and stored at room temperature. Crystallization may occur below 32°F (0°C). STASIS® may be warmed and agitated until dissolution occurs without affecting potency.

**Inactive ingredient**

purified water, glycerin, flavoring

**Principal Display-Stasis 15 cc**

**STASIS®**

Rx only

◀ OPEN HERE

NDC 10129-031-01

Epinephrine-Free

**21%**

**Ferric Sulfate Topical  
Hemostatic Solution**

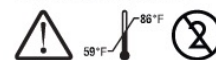
REF 13114

**Contains:** 21% Ferric Sulfate in an aqueous vehicle.

EN - Ferric Sulfate Solution  
DE - Ferric Sulfat-Lösung  
FR - Solution de sulfate ferrique  
NL - Ijzersulfaat Solution  
IT - Ferrico solfato Soluzione  
ES - Solución de sulfato férrico  
PT - Férrico solução de sulfato  
SV - Ferrisulfat Lösning  
DA - Ferrisulfat Solution  
FI - Ferrisulfaattiliuos  
EL - Σιδηρικό θειικό 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](http://www.gingi-pak.com)



**15cc**

Made in USA

# STASIS<sup>®</sup>

R<sub>x</sub> only

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NDC 10129-031-01

Epinephrine-Free

## 21%

### Ferric Sulfate Topical Hemostatic Solution

REF 13114

## 15cc

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Made in USA

Principal Display-Stasis 40 cc

# STASIS<sup>®</sup>

R<sub>x</sub> only

◀ OPEN HERE

NDC 10129-031-02

Epinephrine-Free

## 21%

### Ferric Sulfate Topical Hemostatic Solution

REF 13115

## 40cc

**Contains:** 21% Ferric Sulfate in an aqueous vehicle.

EN - Ferric Sulfate Solution  
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## STASIS

ferric sulfate solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 129-031
Route of Administration	DENTAL, PERIODONTAL, SUBGINGIVAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
FERRIC SULFATE (UNII: 3HWS7HF5XD) (FERRIC CATION - UNII:91O4LML611)	FERRIC CATION	3150 mg in 15 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	0.45 mL in 15 mL

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:10 129-031-01	15 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/26/1987	
2	NDC:10 129-031-02	40 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/26/1987	

**Marketing Information**

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

**Labeler** - Gingi-Pak a Division of the Belport (008480121)**Registrant** - Jeff Nichols (008480121)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Gingi-Pak a Division of the Belport		008480121	manufacture(10 129-031)

Revised: 1/2018

Gingi-Pak a Division of the Belport