

**FERRIC SUBSULFATE- ferric subsulfate solution**  
**CooperSurgical, Inc.**

*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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**AstrinGyn**

**AstrinGyn®**

**(Ferric Subsulfate, Aqueous)**

**REF 6065**

**CONTENTS**

Ferric subsulfate 259mg/g [0.0638gm Fe<sup>3+</sup>/ml]. Preserved with benzalkonium chloride 0.005%. Povidone USP 23.2%. Glycerin USP 13.3%. Purified Water USP.

**DESCRIPTION**

AstrinGyn® (Ferric Subsulfate, Aqueous).

**HOW SUPPLIED**

8 gm single-use glass bottles.

**ACTIONS & USES**

AstrinGyn® is a styptic agent used for achieving local hemostasis. In punch biopsies of the full dermis, the time to achieve hemostasis is typically less than 20 seconds.<sup>1</sup> One method for applying ferric subsulfate solution for dermal use consists of the physician placing fingers at the opposite edges of the wound and stretching the skin. The wound is then wiped with gauze, the ferric subsulfate solution applied, and the tension maintained for approximately 15 seconds.<sup>2</sup>

**WARNINGS**

**For External Use Only.** Should inadvertent ocular administration occur, the eye(s) should be washed immediately with large amounts of water or normal saline, occasionally lifting the upper and lower lids until no evidence of solution remains (approximately 15-20 minutes).

**PRECAUTIONS**

As with all iron solutions applied to dermal surfaces denuded of epithelium or to mucous

membranes, topical application of AstrinGyn® (ferric subsulfate) may result in hyperpigmentation (“tattooing”).<sup>3, 4</sup>

Microscopically, this hyperpigmentation may be observed as ferrugination of collagen fibers and fibrin.<sup>5</sup> In one study of uterine cervical tissue, ferric subsulfate solution penetrated denuded mucosa and produced coagulation necrosis to a maximum depth of 0.6 mm.<sup>6</sup>**In an in vitro study, ferric subsulfate solution produced a radiopacity with a density intermediate between that of water/tissue and calcium.**<sup>7</sup> Should a re-biopsy of the same lesion be required, pathologists and other physicians involved in the care of the patient should be aware of the previous use of ferric subsulfate solution. Previous use of ferric subsulfate solution may result in a histologic artifact upon re-biopsy of heavy pigmentation, similar to hemosiderin, together with shrinkage and discoloration of collagen bundles.<sup>8, 9</sup> Similarly, previous use of ferric subsulfate solution may result in a radiographic artifact.

## **CAUTION**

Federal law (USA) prohibits dispensing without a prescription.

## **STORAGE**

Keep tightly closed and protect from light. **DO NOT** use if seal is broken. Store at room temperature 59°-86°F (15°-30° C).

## **DISPOSAL**

Opened containers with unused portions of product and applicator swabs containing residual product should be placed in a suitable, dry container for later disposal according to local hazardous waste practices. Waste containing AstrinGyn® should not be subjected to any thermal process whether intended for destruction or recycling purposes.

## **REFERENCES**

- Armstrong RB, Nichols J, Pachance J. Punch biopsy wounds treated with Monsel's solution or a collagen matrix. A comparison of healing. Arch. Dermatol 1986;122:546-549.
- Baden HP, Rapid hemostasis with Monsel's solution (letter). Arch Dermatol 1984; 120:708.
- Demis DJ, Clinical dermatology, Hagerstown MD: Harper & Row, 1986; pp. 11-4:1-11-4:5.
- Camisa C, Roberts W. Monsel solution tattooing (letter). J Am Acad Dermatol 1983;8:753-754.
- Amazon K, Robinson MJ, Rywlin AM. Ferrugination caused by Monsel's solution. Clinical observations and experimentation. Am J Dermatopathol 1980;2:197-205.
- Davis JR, Steinbronn KK, Graham AR, Dawson BV. Effects of Monsel's solution in uterine cervix, AM J Clin Pathol 1984;82:332-335.
- Horn MS, Circeo RB, Hassan C. Radiographic artifacts produced by silver nitrate and Monsel's solution (letter). J Am Acad Dermatol 1983;8:560-562.

- Olmstead PM, Lund HZ, Leonard DD. Monsel's solution: a histologic nuisance. J Am Acad Dermatol 1980;3:492-498.
- Wood C, Severin GL. Unusual histiocytic reaction to Monsel's solution. Am J Dermatopathol 1980;2:261-264.

**PRINCIPAL DISPLAY PANEL**

**AstrinGyn®**  
**Ferric Sub sulfate, Aqueous**  
**Contents**  
**One Dozen (12)**  
**8 gm Vials**  
**NDC 59365-6065-1**

**AstrinGyn®** Ferric Sub sulfate, Aqueous

REF #6065

CONTENTS 1 Dozen (12)  
8gm Vials

**CAUTION**  
Federal (USA) Law Prohibits  
Dispensing Without Prescription

**CooperSurgical**  
Trumbull, CT 06611 USA  
Phone: (800) 243-2974  
Fax: (800) 262-0105  
Part # 59365 Revised 3/03

NDC 59365-6065-1

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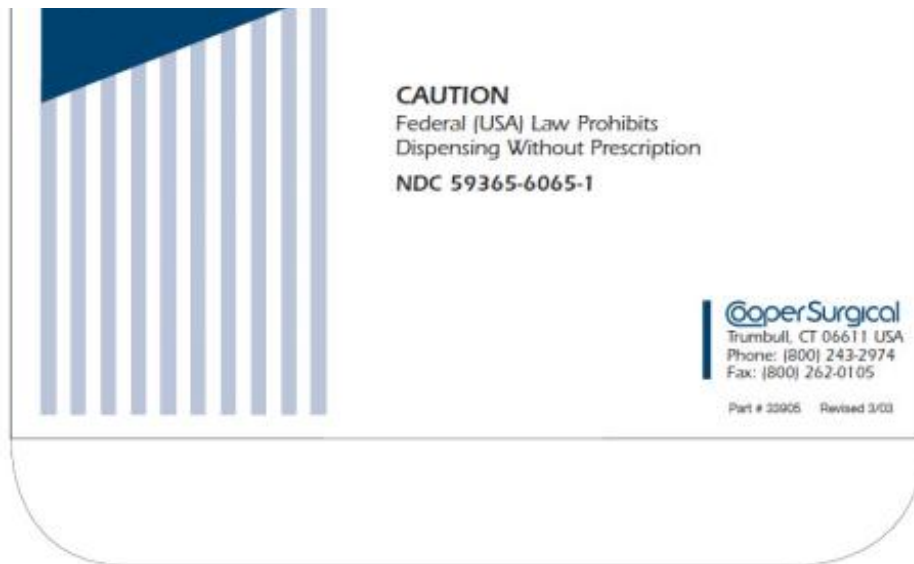
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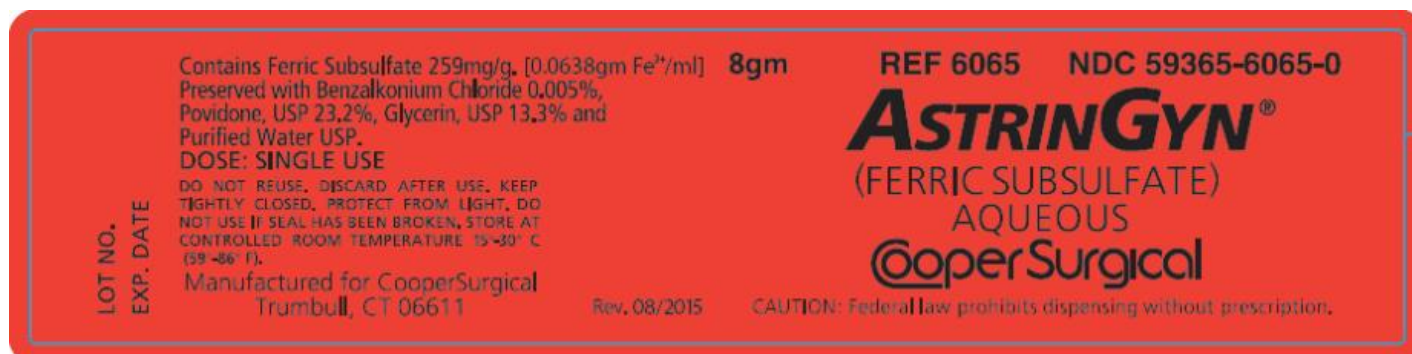
REF #6065

CONTENTS  
 One Dozen (12)  
 8gm Vials



## PRINCIPAL DISPLAY PANEL

**8gm NDC 59365-6065-0**  
**AstrinGyn®**  
**(Ferric Sub sulfate)**  
**Aqueous**



## FERRIC SUBSULFATE

ferric subsulfate solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:59365-6065
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FERRIC SUBSULFATE</b> (UNII: 3QJ8WS6V8H) (FERRIC CATION - UNII:91O4LML611)	FERRIC CATION	259 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
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<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59365-6065-1	12 in 1 CARTON	10/01/1992	
1	NDC:59365-6065-0	8 g in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/01/1992	

**Labeler** - CooperSurgical, Inc. (801895244)

Revised: 5/2016

CooperSurgical, Inc.