

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.

AstrinGyn

AstrinGyn®

(Ferric Subsulfate, Aqueous)

REF 6065

CONTENTS

Ferric subsulfate 259mg/g [0.0638gm Fe ³⁺/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.¹ 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.²

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”).^{3,4}

Microscopically, this hyperpigmentation may be observed as ferrugination of collagen fibers and fibrin.⁵ 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.⁶ **In an in vitro study, ferric subsulfate solution produced a radiopacity with a density intermediate between that of water/tissue and calcium.**⁷ 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.^{8,9} 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

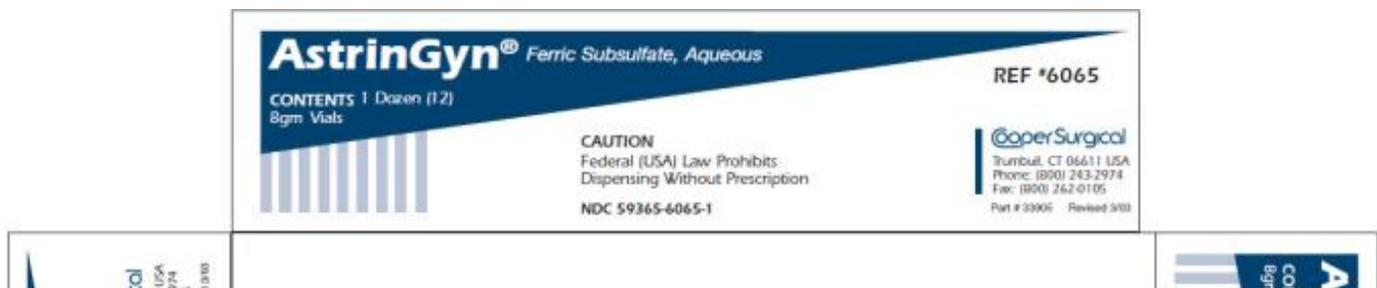
Opened containers with unused portions of product and applicator swabs containing residual product should be placed in a suitable, dry container for later disposal according to local hazardous waste practices. Waste containing AstrinGyn® should not be subjected to any thermal process whether intended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

NDC 59365-6065-1

CoperSurgical
Trumbull, CT 06611
Phone: (800) 243-2974
Fax: (800) 262-0105
Part # 33905 Revised 3/03

stringyn® Ferric Sub sulfate, Aqueous

CONTENTS 1 Dozen (12)
8gm Vials

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PRINCIPAL DISPLAY PANEL

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

Contains Ferric Subsulfate 259mg/g. [0.0638gm Fe²⁺/ml] 8gm
 Preserved with Benzalkonium Chloride 0.005%,
 Povidone, USP 23.2%, Glycerin, USP 13.3% and
 Purified Water USP.

DOSE: SINGLE USE

DO NOT REUSE. DISCARD AFTER USE. KEEP
 TIGHTLY CLOSED. PROTECT FROM LIGHT. DO
 NOT USE IF SEAL HAS BEEN BROKEN. STORE AT
 CONTROLLED ROOM TEMPERATURE 15-30° C
 (59-86° F).

Manufactured for CooperSurgical
 Trumbull, CT 06611

REF 6065 NDC 59365-6065-0

ASTRINGYN[®]
 (FERRIC SUBSULFATE)
 AQUEOUS
 CooperSurgical

LOT NO.
 EXP. DATE

Rev. 08/2015

CAUTION: Federal law prohibits dispensing without prescription.

FERRIC SUBSULFATE

ferric subsulfate solution

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
POVIDONE (UNII: FZ989GH94E)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

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)

