

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.

Ferric Subsulfate Aqueous

DESCRIPTION

Ferric Subsulfate, Aqueous; 8gm single-use glass vials.

CONTENTS

Ferric subsulfate 259mg/g [0.0638gm Fe³⁺/ml]. Preserved with benzalkonium chloride 0.005%. Povidone USP 23.2%. Glycerin USP 13.3%. Purified Water USP.

INDICATIONS AND USAGE

Ferric Subsulfate, Aqueous, 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 of applying ferric subsulfate solution for dermal use consists of the physician placing fingers at the opposite edge 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 eye contact 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 Ferric Subsulfate Aqueous (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 0.6mm.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 Ferric Subsulfate Aqueous 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

Ferric Subsulfate

Aqueous
Contents: 1 dozen (12) 8 gm Vials



PRINCIPAL DISPLAY PANEL

8gm NDC 59365-5006-0
FERRIC SUBSULFATE
AQUEOUS

Contains Ferric Subsulfate 259mg/g [0.0638 gm Fe 3⁺/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 is broken.
 Store at controlled room temperature 15-30°C (59-86°F)
 Manufactured for: Wallach Surgical Devices
 Trumbull, CT 06611 USA

REF 909084

NDC-59365-5006-0

WALLACH
FERRIC SUBSULFATE
AQUEOUS

CAUTION: FEDERAL LAW PROHIBITS
 DISPENSING WITHOUT PRESCRIPTION.

LOT NO.:


FERRIC SUBSULFATE

ferric subsulfate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59365-5006
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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59365-5006-1	12 in 1 CARTON	10/01/1992	
1	NDC:59365-5006-0	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)

