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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Ferric Subsulfate Aqueous

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

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.

INDICATIONS AND USAGE
Ferric Subsulfate, Aqueous, is a stypic 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**


**PRINCIPAL DISPLAY PANEL**

Ferric Subsulfate
Aqueous
Contents: 1 dozen (12) 8gm Vials
PRINCIPAL DISPLAY PANEL

8gm NDC 59365-5006-0
FERRIC SUBSULFATE
AQUEOUS
# FERRIC SUBSULFATE
ferric subsulfate solution

## Product Information

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<th>Product Type</th>
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<th>Item Code (Source)</th>
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<td>Route of Administration</td>
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## Active Ingredient/Active Moiety

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<tr>
<td>FERRIC SUBSULFATE (UNII: 3QJ8WS6V81H)</td>
<td>FERRIC CATION</td>
<td>259 mg in 1 g</td>
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<td>(FERRIC CATION - UNII:91O4LML611)</td>
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## Inactive Ingredients

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<td>POVIDONE (UNII: FZ989GHB4E)</td>
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<td>GLYCERIN (UNII: PDC6A3C0OX)</td>
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## Packaging

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## Marketing Information

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