NDC 59365-6065-0



Ferric Subsulfate, Aqueous

Contains

Ferric subsulfate 259mg/g. Preserved with benzalkonium chloride 0.005%. Povidone USP 23.2%. Glycerin USP 13.3%. Purified Water USP.

Description

AstrinGyn® (Ferric Subsulfate, Aqueous)

How Supplied

8qm single-use glass bottles.

Actions & Uses

AstrinGyn® 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. 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 subsulphate) 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 subsulphate 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. S. 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

- 1 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.
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- 4 Camisa C, Roberts W. Monsel solution tattooing (letter). J Am Acad Dermatol 1983;8:753-754.
- 5 Amazon K, Robinson MJ, Rywlin AM. Ferrugination caused by Monsel's solution. Clinical observations and experimentation. Am J Dermatopathol 1980;2:197-205.
- 6 Davis JR, Steinbronn KK, Graham AR, Dawson BV. Effects of Monsel's solution in uterine cervix, AM J Clin Pathol 1984;82:332-335.
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- 8 Olmstead PM, Lund HZ, Leonard DD. Monsel's solution: a histologic nuisance. J Am Acad Dermatol 1980;3:492-498.
- 9 Wood C, Severin GL. Unusual histiocytic reaction to Monsel's solution. Am J Dermatopathol 1980;2:261-264.

Manufactured for:



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