FERRIC SUBSULFATE AQUEOUS

REF 909084

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

Contents ..................................... Ferric subsulfate 259mg/g. 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. 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.

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"). Microscopically, this hyperpigmentation may be observed as ferrugination of collagen fibers and fibrin. In one study of uterine cervical tissue, ferric subsulfate solution penetrated denuded mucosa and produced coagulation necrosis to a maximum depth of 0.6mm. In an in vitro study, ferric subsulfate solution produced a radiopacity with a density intermediate between that of water/tissue and calcium.

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