

Bulk Drug Substance to be Used in Pharmacy Compounding

Docket No. 98N-0182

Bulk Drug Substance

Ingredient Name: Ferric subsulfate; Monsel's salt NDC 0395-0910-94
Chemical Name: Ferric subsulfate $\text{Fe}_4(\text{OH})_2(\text{SO}_4)_5$
Chemical Grade or Strength: Ferric iron 22 to 24%
How Supplied: Yellow powder
International Pharmacopeial Recognition: Martindale The Extra Pharmacopoeia p.1361
Bibliography: 1) MSDS attached
2) Medline search bibliography attached

Compounded Product

Formulations: Ferric Subsulfate Hemostat (as gel)
Formulation: Ferric subsulfate 50 g
Propylene glycol 10% 36 mL
Strength(s): See above
Route of Administration: Vaginally
Past/Proposed Use: Hemastatic gel. Monsel's solution is available, but is too fluid and runny for this application. The gel formulation is preferred.
Stability Data: None available
Additional Information: None
Nominated by: University of Texas M. D. Anderson Cancer Center
Division of Pharmacy (Box 90)
1515 Holcombe Blvd.
Houston, Texas 77030
tel: (713) 792-2870

1998-3454B1-02-25-BDL12

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TITLE: Punch biopsy wounds treated with Monsel's solution or a collagen matrix. A comparison of healing.

AUTHOR: Armstrong RB; Nichols J; Pachance J

SOURCE: Arch Dermatol 1986 May;122(5):546-9

NLM CIT. ID: 86214141

ABSTRACT: Adjacent punch biopsy wounds in 20 subjects were treated with a collagen matrix or Monsel's solution. Both techniques were easy to use and were hemostatically effective. The collagen matrix produced less inflammation, had a lower incidence of wound infection, was associated with a faster reepithelialization rate, and healed with a modestly better appearance at four weeks than did Monsel's solution.

MAIN MESH SUBJECTS: *Biopsy/ADVERSE EFFECTS
 Collagen/*THERAPEUTIC USE
 Ferric Compounds/*THERAPEUTIC USE
 *Hemostatics
 Iron/*THERAPEUTIC USE
 Sulfates/*THERAPEUTIC USE
 *Wound Healing

ADDITIONAL MESH SUBJECTS: Comparative Study
 Hemostasis
 Human
 Support, Non-U.S. Gov't

PUBLICATION TYPES: JOURNAL ARTICLE

LANGUAGE: Eng

REGISTRY NUMBERS: 0 (Ferric Compounds)

0 (Hemostatics)
 0 (Sulfates)
 1310-45-8 (ferric subsulfate solution)
 7439-89-6 (Iron)
 9007-34-5 (Collagen)



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TITLE: Ferrugination caused by Monsel's solution. Clinical observations and experimentations.

AUTHOR: Amazon K; Robinson MJ; Rywlin AM

SOURCE: Am J Dermatopathol 1980 Fall;2(3):197-205

NLM CIT. ID: 81253487

ABSTRACT: Ferrugination of fibrin, dermal collagen, and striated muscle fibers may result from the application of Monsel's solution (20% ferric subsulfate) for hemostasis to wounds caused by excisions of skin. The collagen fibers in the dermis are coated with a slightly refractile, gray-brown substance which is strongly positive with Perl's reaction for iron. Ferruginated collagen fibers are eliminated through the epidermis as the epidermis regenerates. Some of the ferruginated fibers become calcified. Siderophages are present in these and adjacent areas. Seepage of Monsel's solution into deeper tissues at the site of biopsy may result in ferrugination of skeletal muscle, perichondrium, and even cartilage. We applied Monsel's solution to biopsy sites caused experimentally in a rabbit and confirmed the capacity of the solution to produce ferrugination of collagen fibers and skeletal muscle. Ferrugination of collagen fibers becomes less pronounced as the wounds heal and as iron pigment is taken up by macrophages. Ferruginated fibers of skeletal muscle act as foreign bodies to elicit a granulomatous reaction. Comparison of biopsy sites to which Monsel's solution had been applied with biopsy sites to which the solution had not been applied indicates that the substance does not seem to interfere with the rate of epidermal regeneration. However, when there is injury to skeletal muscle and other deep tissues by Monsel's solution, an inflammatory reaction persists at these sites for weeks.

MAIN MESH SUBJECTS: Ferric Compounds/*ADVERSE EFFECTS
Hemosiderosis/*CHEMICALLY INDUCED
Hemostatics/*ADVERSE EFFECTS
Iron/*ADVERSE EFFECTS
Muscles/*DRUG EFFECTS/PATHOLOGY
Sulfates/*ADVERSE EFFECTS

ADDITIONAL MESH SUBJECTS: Administration, Topical
Aged
Animal
Connective Tissue/DRUG EFFECTS
Female
Human
Male
Rabbits
Skin/PATHOLOGY

PUBLICATION JOURNAL ARTICLE

TYPES:

LANGUAGE: Eng

REGISTRY 0 (Ferric Compounds)

NUMBERS: 0 (Hemostatics)

0 (Sulfates)

1310-45-8 (ferric subsulfate solution)

7439-89-6 (Iron)



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Order Documents		92 71 Other Years	Log off IGM	



TITLE: Effects of Monsel's solution in uterine cervix.
AUTHOR: Davis JR; Steinbronn KK; Graham AR; Dawson BV
SOURCE: Am J Clin Pathol 1984 Sep;82(3):332-5
NLM CIT. ID: 84277629
ABSTRACT: Monsel's solution applied to biopsy sites causes tissue necrosis that can persist for two weeks and impede reepithelialization. Granulation tissue in the healing phase contains iron pigment residue from the agent. The pigment encrusts upon collagen and is present in siderophages for up to three months. Occasionally pigment or necrotic residues incite a foreign body giant cell reaction. Awareness is recommended in order to avoid confusion. The agent's potential effect upon the basic disease is discussed.

MAIN MESH SUBJECTS: Cervix Uteri/*DRUG EFFECTS
 Ferric Compounds/*ADVERSE EFFECTS
 Iron/*ADVERSE EFFECTS/ANALYSIS
 Sulfates/*ADVERSE EFFECTS

ADDITIONAL MESH SUBJECTS: Female
 Foreign-Body Reaction/CHEMICALLY INDUCED
 Granuloma/CHEMICALLY INDUCED
 Human
 Necrosis
 Phagocytosis
 Pigmentation
 Wound Healing/DRUG EFFECTS

PUBLICATION TYPES: JOURNAL ARTICLE

LANGUAGE: Eng
REGISTRY NUMBERS: 0 (Ferric Compounds)
 0 (Sulfates)
 1310-45-8 (ferric subsulfate solution)
 7439-89-6 (Iron)



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TITLE: Monsel's solution-induced artifact in the uterine cervix.

AUTHOR: Spitzer M; Chernys AE

AUTHOR AFFILIATION: Department of Obstetrics and Gynecology, Queens Hospital Center, Jamaica, NY 11432, USA.

SOURCE: Am J Obstet Gynecol 1996 Nov;175(5):1204-7

NLM CIT. ID: 97097948

ABSTRACT: We documented and quantified Monsel's solution-related artifacts after cervical biopsies. All loop electrosurgical cone biopsy specimens over a 3-month period were reviewed for necrosis artifact of the surface epithelium. The degree of change was quantified and correlated with the antecedent use of Monsel's solution. Twenty-four cone biopsy specimens were evaluated. Three of the eight cone biopsy specimens obtained fewer than 10 days after the use of Monsel's solution showed definite changes. Between 10 and 18 days after the use of Monsel's solution, four of eight specimens showed change. After 18 days, none of eight specimens showed change. One specimen at 18 days showed focal changes that seemed to be related to the use of an unusually large amount of Monsel's solution, because the patient had had six biopsies within 2 days. The routine use of Monsel's solution may interfere with the ability to recognize and characterize disease process in cone biopsy specimens when the cone procedure is done within 3 weeks after the use of Monsel's solution.

MAIN MESH SUBJECTS: Cervix Uteri/DRUG EFFECTS/*PATHOLOGY
 Ferric Compounds/*ADVERSE EFFECTS
 Sulfates/*ADVERSE EFFECTS

ADDITIONAL MESH SUBJECTS: Artifacts
 Biopsy
 Female
 Human

PUBLICATION TYPES: JOURNAL ARTICLE

LANGUAGE: Eng

REGISTRY NUMBERS: 0 (Ferric Compounds)
 0 (Sulfates)
 1310-45-8 (ferric subsulfate solution)



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FERRIC SUBSULFATE SOLUTION

Has been used topically to stop cervical bleeding.

Can cause skin pigmentation. Toxicological information is lacking. May cause eye irritation. Acute exposure can cause corrosion to G.I. tract lining. Irritant to upper respiratory tract, eye, skin and mucous membranes. Can produce skin rash and anaphylactoid reactions, vomiting, diarrhea and circulatory collapse. Chronic exposures can produce liver and pancreatic damage.

REFERENCES

1. Spitzer M, Chernys AE. Monsel's solution-induced artifact in the uterine cervix. *Am J Obstet Gynecol* 1996; 175(5):1204-7.
2. Manca DP. Stopping cervical bleeding. *Can Fam Physician* 1997; 43:2121.
3. Su GB. [Clinical experience on efficacy of Monsel's solution (author's transl)] *Chung Hua Wai Ko Tsa Chih* 1981; 19(11):685-6.
4. Manca DP. Practice tips. Mole no more. *Can Fam Physician* 1997; 43:1359.
5. Soyle M, Warwick A, Redman C, et al. Does application of Monsel's solution after loop diathermy excision of the transformation zone reduce post operative discharge? Results of a prospective randomised controlled trial [see comments]. *Br J Obstet Gynaecol* 1992; 99(12):1023-4.
6. Ratcliff CR. Preventing cervical bleeding with Monsel's solution. *Oncol Nurs Forum* 1992; 19(4):664.
7. Lopes A, Monaghan JM, Robertson G, et al. Does application of Monsel's solution after loop diathermy excision of the transformation zone reduce post-operative discharge? [letter; comment] *Br J Gynaecol* 1993; 100(8):794.
8. Jetmore AB, Heryer JW, Conner WE. Monsel's solution: a kinder, gentler hemostatic. *Dis Colon Rectum* 1993; 36(9):866-7.