A. INGREDIENT NAME:

FERRIC SULFATE HYDRATE

B. Chemical Name:

Diiron Trisulfate

C. Common Name:

Ferric Sulfate, Iron Persulfate, Iron Sesquisulfate, Iron Sulfate (2:3), Iron (3+) sulfate, Iron Tersulfate, Sulfuric Acid, Iron (3+) Salt (3:2)

D. Chemical grade or description of the strength, quality, and purity of the ingredient:

Purity: 73.0 min.
A solution responds to the test for ferric iron and sulfate.

E. Information about how the ingredient is supplied:

Grayish-white powder, or Rhombic or Rhombohedral crystals, very hygroscopic, commercial product usually contains about 20% water and is yellowish in color.

F. Information about recognition of the substance in foreign pharmacopeias:

G. Bibliography of available safety and efficacy data including peer reviewed medical literature:

Fuks, A. B., Holan, G., and Davis, J. M. Ferric sulfate versus dilute formocresol in pulpotomized primary molars: long-term follow up. *Pediatric Dentistry*, 1997: 19(5): 327-330.

Jeansonne, B. G., Boggs, W. S., and Lemon, R. R. Ferric sulfate hemostasis: efect on osseous wound healing. II. With curettage and irrigation. *Journal of Endodontics*, 1993; 19(4): 174-176.

Fei, A. L., Udin, r. d., and Johnson, R. A clinical study of ferric sulfate as a pulpotomy agent in primary teeth. *Pediatric Dentistry*, 1991; 13(6): 327-332.

Shaw, D. H., Krejci, R. F., and Kalkwarf, K. L. Gingival response to retraction by ferric sulfate. *Operative Dentistry*, 1983; 8(4): 142-147.

H. Information about dosage forms used:

Solution

I. Information about strength:

J. Information about route of administration:

K. Stability data:

Store at room temperature. Protect from light.
Stable

L. Formulations:

Ferrous Sulphate.....400gm
Sulphuric Acid.....78gm
Nitric Acid, Distilled water - a significant quantity.
See file for compounding formulation

M. Miscellaneous Information:

Database: Medline <1966 to present>

<1>
Unique Identifier
97406844
Authors
Fuks AB. Holan G. Davis JM. Eidelman E.
Title
Ferric sulfate versus dilute formocresol in pulpotomized primary molars: long-term follow up.
Source
Pediatric Dentistry. 19(5):327-30, 1997 Jul-Aug.
Abstract
The aim of this study was to compare the effect of ferric sulfate (FS) to that of dilute formocresol (DFC) as pulp dressing agents in pulpotomized primary molars. Ninety-six primary molars in 72 children were treated by a conventional pulpotomy technique. Fifty-eight teeth were treated by a FS solution for 15 sec, rinsed, and covered by zinc oxide-eugenol paste (ZOE). In another 38 teeth, a cotton pellet moistened with 20% DFC was placed for 5 min, removed, and the pulp stumps were covered by ZOE paste. The teeth of both groups were sealed by a second layer of intermediate restorative material (IRM) and restored with a stainless steel crown. This is a report of the clinical and radiographic examination of 55 teeth dressed with FS and 37 teeth fixed with DFC, that have been treated 6 to 34 months previously (mean 20.5 months). Four teeth were excluded from the study due to failure of the patient to present for recall. Success rates of 92.7% for the FS, and of 83.8% for the DFC were not significantly different. Four teeth (7.2%) of the FS group and two (5.4%) of the DFC group presented internal resorption. Inter-radicular radiolucencies were observed in two teeth of the FS group and three teeth of the DFC group. The latter also presented periapical lesions. Success rates of both groups were similar to those of previous studies utilizing the traditional Buckley's formocresol.

<2>
Unique Identifier
97391944
Authors
Kim S. Rethnam S.
Title
Hemostasis in endodontic microsurgery.

Unique Identifier
93316024
Authors
Jeansonne BG. Boggs WS. Lemon RR.
Title
Ferric sulfate hemostasis: effect on osseous wound healing. II. With curettage and irrigation.
Source
Journal of Endodontics. 19(4):174-6, 1993 Apr.
Abstract
Hemorrhage control is often a problem for the clinician during osseous surgery. Ferric sulfate is an effective hemostatic agent, but with prolonged application to an osseous defect can cause persistent inflammation and delayed healing. The purpose of this investigation was to evaluate the effectiveness of ferric sulfate as a hemostatic agent and to determine its effect on healing after thorough curettage and irrigation from osseous surgical wounds. Standard size osseous defects were created bilaterally in the mandibles of rabbits. Ferric sulfate was placed in one defect until hemostasis was obtained; the contralateral defect was allowed to fill with blood and clot. After 5 min both defects were curetted and irrigated. The repair of the defects was evaluated histologically at 18 and 46 days. There were no significant differences between the ferric sulfate-treated defects and the untreated controls. When adequately curetted and irrigated from the surgical site prior to closure, ferric sulfate did not cause persistent inflammation or delay osseous repair in comparison to controls.

<6>
Unique Identifier
93316023
Authors
Lemon RR. Steele PJ. Jeansonne BG.
Title
Ferric sulfate hemostasis: effect on osseous wound healing. Left in situ for maximum exposure.
Source
Journal of Endodontics. 19(4):170-3, 1993 Apr.
Abstract
Ferric sulfate solution is an accepted soft tissue hemostatic agent for use in dermatology and dentistry. This study was designed to test its effect on osseous healing when used during surgery to control osseous hemorrhage. Standardized osseous defects were created bilaterally in the naturally edentulous zone in rabbit mandibles. The

control site was sutured immediately after clot formation in the defect. The contralateral experimental site received ferric sulfate application until complete hemostasis was achieved. The defect was filled with ferric sulfate solution to maximize any effect on healing and then closed with sutures. The experimental and control specimens were examined histologically after 18 and 46 days and scored for healing. Statistical analysis by Wilcoxon signed rank test showed significant adverse effects on osseous healing when ferric sulfate solution was left in situ.

<7>
Unique Identifier
93181319
Authors
Fei AL. Udin RD. Johnson R.
Title
A clinical study of ferric sulfate as a pulpotomy agent in primary teeth.
Source
Pediatric Dentistry. 13(6):327-32, 1991 Nov-Dec.
Abstract
Pulpotomies were performed on 83 primary molars in 62 patients. Ferric sulfate or formocresol was placed on the pulpal stumps, and teeth were followed for 3-, 6-, and 12-month periods. After the one-year follow-up, 28 of 29 teeth treated with ferric sulfate (FS group) were considered successful and 21 of 27 teeth treated with formocresol (FC group) were judged to be successful. The FS group demonstrated greater combined clinical and radiographic success than the FC group at the one-year recall ($P < 0.05$). Although the results of this study are promising, further study with longer observation periods is warranted before this technique can be recommended.

Source
Dental Clinics of North America. 41(3):499-511, 1997 Jul.
Abstract
There are numerous ways to achieve hemostasis. With the abundance of hemostatic agents available and with the introduction of new products, one has to make an objective decision. A good agent achieves hemostasis within a short period of time, is easy to manipulate, is biocompatible, does not impair or retard healing, must be relatively inexpensive, is reliable, and works best for the particular surgical procedure. With these purposes in mind, the following sequence is recommended to achieve hemostasis during endodontic microsurgery. I. Presurgical: Give 2 to 3 Carpules of 1:50,000 epinephrine local anesthetic with multiple infiltration sites throughout the entire surgical field. II. Surgical: A. Remove all granulation tissue. B. Place an epinephrine pellet into the bony crypt followed by dry sterile cotton pellets. Apply pressure for 2 minutes. Remove all the cotton pellets except the first epinephrine pellet. Continue with the surgical procedure and remove the epinephrine pellet before final irrigation and closure. C. Alternatively, calcium sulfate can be mixed into a thick putty and packed against the bone cavity. Because it is a biodegradable material, calcium sulfate can be left in situ. In fact, in large bone defects and through-and-through lesions, additional calcium sulfate can be placed to fill the entire bone cavity as a barrier material. Healing is more predictable with little chance of scar tissue formation. Calcium sulfate resorbs in 2 to 4 weeks. D. Small bleeding sites in the bone can be brushed with ferric sulfate solution. III. Postsurgical: Tissue compression before and after suturing cuts down on postsurgical bleeding and swelling. Hemostasis is imperative in endodontic microsurgery for better visualization, a good environment for placement of retrograde filling material, and a more efficient surgical procedure with less blood loss.

<3>
Unique Identifier
84144452
Authors
Shaw DH. Krejci RF. Kalkwarf KL. Wentz FM.
Title
Gingival response to retraction by ferric sulfate (Astringedent).
Source
Operative Dentistry. 8(4):142-7, 1983 Autumn.

FERRIC SULFATE HYDRATE

Used in solution form to control osseous hemorrhaging and as a pulpotomy agent in teeth.

It has caused liver and kidney damage, G.I. tract irritation, shock, eye, skin and respiratory irritation.

REFERENCES

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2. Jeansonne BG, Boggs WS, Lemon RR. Ferric sulfate hemostasis: effect on osseous wound healing. II. With curettage and irrigation. J Endodont 1993; 19(4):174-6.

3. Lemon RR, Steele PJ, Jeansonne BG. Ferric sulfate hemostasis: effect on osseous wound healing. Left in situ for maximum exposure. J Endodont 1993; 19(4):170-3.

4. Fei AL, Udin RD, Johnson R. A clinical study of ferric sulfate as a pulpotomy agent in primary teeth. Pediatr Dent 1991; 13(6):327-32.

5. Shaw DH, Krejci RF, Kalkwarf KL, et al. Gingival response to retraction by ferric sulfate (Astringedent). Operative Dent 1983; 8(4):142-73.

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9. Fuks AB, Holan G, Davis JM, et al. Ferric sulfate versus dilute formocresol in pulpotomized primary molars: long-term follow up. Pediatr Dent 1997; 19(5):327-30.

10. Kim S, Rethnam S. Hemostasis in endodontic microsurgery. Dent Clin North Am 1997 41(3):499-511.

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