



NEW P/G Fulvicin P/G

griseofulvin [ultramicrosize], USP
(specially processed) 125 mg. tablets

Clinical Considerations: INDICATIONS FULVICIN P/G Tablets are indicated for the treatment of ringworm infections of the skin, hair, and nails, namely: tinea corporis, tinea pedis, tinea cruris, tinea barbae, tinea capitis, tinea unguium (onychomycosis) when caused by one or more of the following genera of fungi: *Trichophyton rubrum*, *Trichophyton tonsurans*, *Trichophyton mentagrophytes*, *Trichophyton interdigitalis*, *Trichophyton verrucosum*, *Trichophyton megnini*, *Trichophyton gallinae*, *Trichophyton crateriform*, *Trichophyton sulphureum*, *Trichophyton schoenleinii*, *Microsporum audouinii*, *Microsporum canis*, *Microsporum gypsum*, and *Epidermophyton floccosum*. Note: Prior to therapy, the type of fungi responsible for the infection should be identified. The use of this drug is not justified in minor or trivial infections which will respond to topical agents alone. Griseofulvin is not effective in the following: Bacterial infections, Candidiasis (Moniliasis), Histoplasmosis, Actinomycosis, Sporotrichosis, Chromoblastomycosis, Coccidioidomycosis, North American Blastomycosis, Cryptococcosis (Torulosis), Tinea versicolor, and Nocardiosis.

CONTRAINDICATIONS This drug is contraindicated in patients with porphyria, hepatocellular failure, and in individuals with a history of hypersensitivity to griseofulvin.

WARNINGS Prophylactic Usage: Safety and efficacy of griseofulvin for prophylaxis of fungal infections have not been established.

Toxicology Chronic feeding of griseofulvin, at levels ranging from 0.5-2.5% of the diet, resulted in the development of liver tumors in several strains of mice, particularly in males. Smaller particle sizes result in an enhanced effect. Lower oral dosage levels have not been tested. Subcutaneous administration of relatively small doses of griseofulvin once a week during the first three weeks of life has also been reported to induce hepatomata in mice. Although studies in other animal species have not yielded evidence of tumorigenicity, these studies were not of adequate design to form a basis for conclusions in this regard. In subacute toxicity studies, orally administered griseofulvin produced hepatocellular necrosis in mice, but this has not been seen in other species. Disturbances in porphyrin metabolism have been reported in griseofulvin-treated laboratory animals. Griseofulvin has been reported to have a colchicine-like effect on mitosis and cocarcinogenicity with methylcholanthrene in cutaneous tumor induction in laboratory animals.

Usage in Pregnancy: The safety of this drug during pregnancy has not been established.

Animal Reproduction Studies: It has been reported in the literature that griseofulvin was found to be embryotoxic and teratogenic on oral administration to pregnant rats. Pups with abnormalities have been reported in the litters of a few bitches treated with griseofulvin. Additional animal reproduction studies are in progress. Suppression of spermatogenesis has been reported to occur in rats, but investigation in man failed to confirm this.

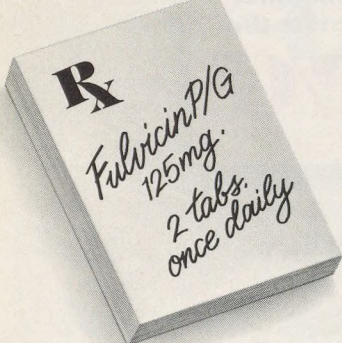
PRECAUTIONS Patients on prolonged therapy with any potent medication should be under close observation. Periodic monitoring of organ system function, including renal, hepatic, and hematopoietic, should be done. Since griseofulvin is derived from species of penicillin, the possibility of cross sensitivity with penicillin exists; however, known penicillin-sensitive patients have been treated without difficulty. Since a photosensitivity reaction is occasionally associated with griseofulvin therapy, patients should be warned to avoid exposure to intense natural or artificial sunlight. Should a photosensitivity reaction occur, lupus erythematosus may be aggravated. Griseofulvin decreases the activity of warfarin-type anticoagulants so that patients receiving these drugs concomitantly may require dosage adjustment of the anticoagulant during and after griseofulvin therapy. Barbiturates usually depress griseofulvin activity, and concomitant administration may require a dosage adjustment of the antifungal agent.

ADVERSE REACTIONS When adverse reactions occur, they are most commonly of the hypersensitivity type, such as skin rashes, urticaria, and rarely, angioneurotic edema, and may necessitate withdrawal of therapy and appropriate countermeasures. Paresthesias of the hands and feet have been reported rarely after extended therapy. Other side effects reported occasionally are oral thrush, nausea, vomiting, epigastric distress, diarrhea, headache, fatigue, dizziness, insomnia, mental confusion, and impairment of performance of routine activities. Proteinuria and leukopenia have been reported rarely. Administration of the drug should be discontinued if granulocytopenia occurs. When rare, serious reactions occur with griseofulvin, they are usually associated with high dosages, long periods of therapy, or both.

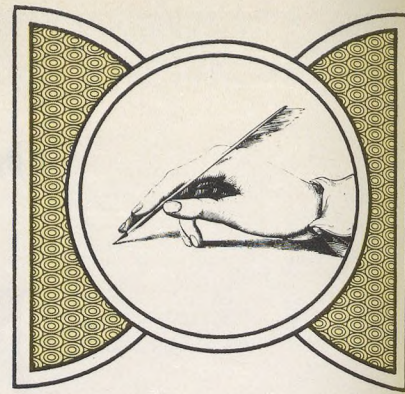
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JANUARY 1977

For more complete details, consult package insert or Schering literature available from your Schering Representative or Professional Services Department, Schering Corporation, Kenilworth, New Jersey 07033.



Letters to the Editor



Treatment of Whiplash Injury

To The Editor:

I read with interest the article on cervical myelopathy secondary to cervical spondylosis by Dr. Donald Peterson, (*J Fam Pract* 4:233, 1977). It is a timely article in that one of the etiological causes, as he mentions in his article, is remote head and neck trauma, and the incidence of so-called whiplash injuries to the neck is increasing. Dr. James Cyriax, of London, England, who is visiting Professor in Orthopedic Medicine to the University of Rochester, Rochester, New York, feels strongly that in whiplash injuries of the neck, one of the problems is a cervical disc derangement with a protrusion of the disc fragment posteriorly, with impingement on, and stretching of, the posterior longitudinal ligament. For years, he has strongly recommended the manipulative reduction of this fragment of cervical disc, as early as possible after it has been detected, to allow a repositioning of the posterior longitudinal ligament in its normal place, and a reduction of the tendency to develop osteophytes at this location. As you know, osteophytes tend to grow out to fill the space between the bone and the ligament, and if no fragment is exerting pressure and stretching this ligament then, in theory, the osteophyte should not occur.

I would recommend that anyone who is interested in whiplash injury read Dr. Cyriax' *Textbook of Orthopedic Medicine* (Baltimore, Williams & Wilkins, 1975) with particular reference to his management of whiplash injuries on pages 142-144 of the sixth edition. I have been using his techniques now for two or three years, and find that early reduction of the fragment of disc restores full range of movement to the whiplashed neck.

Again, congratulations on this interesting article, and perhaps something in the way of preventive medicine may be done to forestall the increasing frequency of this cervical myelopathy.

D. M. Fraser, MD
St. Catherines, Ontario

Family-Oriented Medical Record

To The Editor:

The recent article by Drs. NT Grace, EM Neal, CE Wellock, et al, regarding a reorientation of the problem

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oriented medical record for family practice (*J Fam Pract* 4:91, 1977) was quite interesting. We have tried a variety of formats and, while we can see certain advantages to the system presented, we note several significant problems.

Generally speaking, a "practical medical record" should do more than simply record. It should allow for quick recording and recovery of information in an organized manner and remind the physician of health-maintenance timing as well as allow for individual flexibility. Too many sheets of paper clutter the chart and frustrate the physician and, therefore, I would make the following specific suggestions:

1. Family Problem List:
 - a. Allow for a greater number of problems, with differentiation between chronic and short term types;
 - b. Allow for enlargement of one individual problem list without having to change entire sheet (paste-ons, etc);
 - c. Provide a place for date of onset and date of resolution for each problem.
2. Family Information:
 - a. Should have some definite place for familial diseases;
 - b. Should have room for changes in phone number and address;
 - c. Provide for social history (ETOH, cigarettes, stress, etc) here, or on individual data sheet.
3. Individual Data Sheet:
 - a. Continuing medication chart should allow for changes in dosage or frequency of medications;
 - b. Immunization sheet gives no indication of when these should be done;
 - c. No indication is made for when other screening measures should be done, and no mention is made of prophylactic counseling.
4. Physiological Data Sheets

a. These should be flexible and allow for individual or family orientation. How many patients have most of these tests done, or have repeats on tests such as IVP, barium enema, pulmonary function tests, etc? These should be more than just another place to record data, and should help organize and simplify the patients' care.

b. This would be a good place to provide for recommended preventive maintenance.

I think the concept of a family-oriented record is an interesting and viable one, and I thank you for sharing it with us.

Henry R. Ivey, MD

Chief Resident in Family Practice
First Colonial Family Practice Center
Virginia Beach, Virginia

The above letter was referred to Dr. Grace who responds as follows:

As we mentioned in our article, the family-oriented medical record as used in our practice is not in its ultimate form but is rather in a state of evolution. Its major concepts must be adapted to the individual practice of the family physician. The ideas that Dr Ivey presents in his letter are good ones, and each point that he raises has been considered by us in the development of our record to its present state. Obviously, implementation of his ideas would result in a slightly different format than ours.

This is the value of presenting ideas in the Journal — it gives impetus to practicing physicians selecting and adapting ideas to the needs of their own practice. The most important concept that we wanted to present was that of the *Family Problem List*, where both individual problems and problems of the family as a whole are grouped. This has proved to be of great practical value, and we look forward to seeing further adaptation of this idea by other family-oriented physicians.

Nicholas T. Grace, MD
Healdsburg, California

Brief Summary of Prescribing Information Elase® Ointment

(fibrinolysin and desoxyribonuclease, combined [bovine] ointment)

Description. Elase Ointment is a combination of two lytic enzymes, fibrinolysin and desoxyribonuclease, supplied in an ointment base of liquid petrolatum and polyethylene. The fibrinolysin component is derived from bovine plasma and the desoxyribonuclease is isolated in a purified form from bovine pancreas. The fibrinolysin used in the combination is activated by chloroform.

Action. Combination of these two enzymes is based on the observation that purulent exudates consist largely of fibrinous material and nucleoprotein. Desoxyribonuclease attacks the desoxyribonucleic acid (DNA) and fibrinolysin attacks principally fibrin of blood clots and fibrinous exudates.

The activity of desoxyribonuclease is limited principally to the production of large polynucleotides, which are less likely to be absorbed than the more diffusible protein fractions liberated by certain enzyme preparations obtained from bacteria. The fibrinolytic action of the enzymes in Elase Ointment is directed mainly against denatured proteins, such as those found in devitalized tissue, while protein elements of living cells remain relatively unaffected.

Elase Ointment is a combination of active enzymes. This is an important consideration in treating patients suffering from lesions resulting from impaired circulation.

The enzymatic action of Elase helps to produce clean surfaces and thus supports healing in a variety of exudative lesions.

Indications. Elase Ointment is indicated for topical use as a debriding agent in a variety of inflammatory and infected lesions. These include: (1) general surgical wounds; (2) ulcerative lesions—trophic, decubitus, stasis, arteriosclerotic; (3) second- and third-degree burns; (4) circumcision and episiotomy. Elase is used intravaginally in: (1) cervicitis—benign, postpartum, and postcoital; and (2) vaginitis.

Precautions. The usual precautions against allergic reactions should be observed, particularly in persons with a history of sensitivity to materials of bovine origin or to mercury compounds.

Adverse Reactions. Side effects attributable to the enzymes have not been a problem at the dose and for the indications recommended herein. With higher concentrations, side effects have been minimal, consisting of local hyperemia.

Chills and fever attributable to antigenic action of profibrinolysin activators of bacterial origin are not a problem with Elase.

Dosage and Administration. Because the conditions for which Elase Ointment is helpful vary considerably in severity, dosage must be adjusted to the individual case; however, the following general recommendations can be made.

Successful use of enzymatic debridement depends on several factors: (1) dense, dry eschar, if present, should be removed surgically before enzymatic debridement is attempted; (2) the enzyme must be in constant contact with the substrate; (3) accumulated necrotic debris must be periodically removed; (4) the enzyme must be replenished at least once daily; and (5) secondary closure or skin grafting must be employed as soon as possible after optimal debridement has been attained. It is further essential that wound-dressing techniques be performed carefully under aseptic conditions and that appropriate systemically acting antibiotics be administered concomitantly if, in the opinion of the physician, they are indicated.

General Topical Uses: Local application should be repeated at intervals for as long as enzyme action is desired. After application, Elase Ointment becomes rapidly and progressively less active and is probably exhausted for practical purposes at the end of 24 hours.

Intravaginal Use: In mild to moderate vaginitis and cervicitis, 5 ml of Elase Ointment should be deposited deep in the vagina once nightly at bedtime for approximately five applications, or until the entire contents of one 30-g tube has been used. The patient should be checked by her physician to determine possible need for further therapy. In more severe cervicitis and vaginitis, some physicians prefer to initiate therapy with an application of Elase (fibrinolysin and desoxyribonuclease, combined [bovine]) in solution. See Elase package insert.

How Supplied. NDC 0071-1121-53 Elase Ointment, 30-g. The 30-g tube contains 30 units of fibrinolysin and 20,000 units of desoxyribonuclease with 0.12 mg thimerosal (mercury derivative) in a special ointment base of liquid petrolatum and polyethylene. For gynecologic use, six disposable vaginal applicators (V-Applicator™) as a separate package are available for this tube when required to facilitate administration of the proper dose.

NDC 0071-1121-52 Elase Ointment, 10-g. The 10-g tube contains 10 units of fibrinolysin and 6,666 units of desoxyribonuclease with 0.04 mg thimerosal (mercury derivative) in a special ointment base of liquid petrolatum and polyethylene.

This product also contains sodium chloride and sucrose as incidental ingredients.

PD-JA-1850-1-P (3-77)

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Parke, Davis & Company
Detroit, MI 48232