

Oral and Intravenous Brief Summary

Indications: For the treatment of susceptible gram-positive and gram-negative organisms. For full list of approved indications consult labeling.

Contraindications: Hypersensitivity to any tetracycline.

Warnings: In the presence of renal dysfunction, intravenous use, particularly in pregnancy, in daily doses exceeding 2 grams has been associated with deaths through liver failure. When need for intensive treatment outweighs potential dangers, perform renal and liver function tests before and during therapy; also follow serum concentrations. In renal impairment, usual doses may lead to excessive accumulation and liver toxicity. Under such conditions, use lower total doses, and, in prolonged therapy, determine serum levels.

This hazard is of particular importance in parenteral use in pregnant or postpartum patients with pyelonephritis. In such cases, the blood level should not exceed 15 mcgm/ml and liver function tests should be made at frequent intervals. Do not prescribe other potentially hepatotoxic drugs concomitantly. **THE USE OF TETRACYCLINES DURING TOOTH DEVELOPMENT (LAST HALF OF PREGNANCY, INFANCY AND CHILDHOOD TO THE AGE OF 8 YEARS) MAY CAUSE PERMANENT DISCOLORATION OF THE TEETH (YELLOW-GRAY-BROWN).** This is more common during long-term use but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. **TETRACYCLINES, THEREFORE, SHOULD NOT BE USED IN THIS AGE GROUP UNLESS OTHER DRUGS ARE NOT LIKELY TO BE EFFECTIVE OR ARE CONTRAINDICATED.** Photosensitivity, manifested by an exaggerated sunburn reaction, has been observed in some individuals taking tetracyclines. Advise patients apt to be exposed to direct sunlight or ultraviolet light that such reaction can occur, and discontinue treatment at first evidence of skin erythema. Studies to date indicate that photosensitivity is rarely reported with MINOCIN *Minocycline HCl*. The antianabolic action of tetracycline may cause an increase in BUN. In patients with significantly impaired renal function, higher serum levels of tetracycline may lead to azotemia, hyperphosphatemia and acidosis. CNS side effects (lightheadedness, dizziness, vertigo) have been reported, may disappear during therapy, and always disappear rapidly when drug is discontinued. Caution patients who experience these symptoms about driving vehicles or using hazardous machinery while taking this drug.

Pregnancy: In animal studies, tetracyclines cross the placenta, are found in fetal tissues, and can have toxic effects on the developing fetus (often related to retardation of skeletal development). Embryotoxicity has been noted in animals treated early in pregnancy. **Newborns, infants and children:** All tetracyclines form a stable calcium complex in any bone-forming tissue. Prematures, given oral doses of 25 mg/kg every 6 hours, demonstrated a decrease in fibula growth rate, reversible when drug was discontinued. Tetracyclines are present in the milk of lactating women who are taking a drug of this class.

Precautions: Use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, discontinue and institute appropriate therapy. In venereal diseases, when coexistent syphilis is suspected, darkfield examination should be done before treatment is started and blood serology repeated monthly for at least four months. Patients on anticoagulant therapy may require downward adjustment of such dosage. Test for organ system dysfunction (e.g., renal, hepatic and hematopoietic) in long-term use. Treat all Group A beta-hemolytic streptococcal infections for at least 10 days. Avoid giving tetracycline in conjunction with penicillin.

Adverse Reactions: GI: (with both oral and parenteral use): anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocolitis, inflammatory lesions (with monilial overgrowth) in anogenital region. **Skin:** maculopapular and erythematous rashes, folliculitis, dermatitis (uncommon). Photosensitivity is discussed above ("Warnings"). Pigmentation of the skin and mucous membranes has been reported. **Renal toxicity:** rise in BUN, dose-related (see "Warnings"). **Hypersensitivity reactions:** urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, pericarditis, exacerbation of systemic lupus erythematosus. In young infants, bulging fontanelles have been reported following full therapeutic dosage, disappearing rapidly when drug was discontinued. **Blood:** hemolytic anemia, thrombocytopenia, neutropenia, eosinophilia. **CNS:** (see "Warnings"). When given in high doses, tetracyclines may produce brown-black microscopic discoloration of thyroid glands; no abnormalities of thyroid function studies are known to occur.

NOTE: Rapid administration is to be avoided. Parenteral therapy is indicated only when oral therapy is not adequate or tolerated. Oral therapy should be instituted as soon as possible. If intravenous therapy is given over prolonged periods of time, thrombophlebitis may result.

Concomitant therapy: Antacids containing aluminum, calcium, or magnesium impair absorption; do not give to patients taking oral minocycline. Studies to date indicate that absorption of MINOCIN is not notably influenced by foods and dairy products.

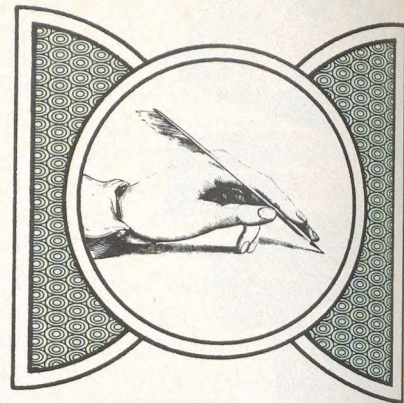
CNS side effects including lightheadedness, dizziness, or vertigo have been reported with MINOCIN. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery while on minocycline therapy. Enamel hypoplasia/tooth staining may occur in children under eight years of age.

References: 1. MacCulloch D, Richardson RA, Allwood GK: The penetration of doxycycline, oxytetracycline and minocycline into sputum. *N Z Med J* 80: 300-302, 1974. 2. Data on file, Lederle Laboratories, Pearl River, New York. 3. Iwasawa T, Kido T: Clinical and experimental studies on minocycline. *Jpn J Antibiot* 22: 511-521, 1969.

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Letters to the Editor



The Journal welcomes Letters to the Editor; if found suitable, they will be published as space allows. Letters should be typed double-spaced, should not exceed 400 words, and are subject to abridgment and other editorial changes in accordance with journal style.

Cardiopulmonary Resuscitation Training To the Editor:

I read with interest the article on "Cardiopulmonary Resuscitation Training in a Family Practice Residency" (*J Fam Pract* 12:1013, 1981). I spent about two years at the University of Alabama in Tuscaloosa on the staff of the residency program. I find that the training of residents at the level of basic cardiac life support is inadequate for general medicine, at least in the family practice I am engaged in and have been exposed to during my ten years in family practice.

At Tuscaloosa we initiated a two-stage cardiopulmonary resuscitation program. The first stage involved the incoming first year resident class in their indoctrination, during which they received advanced cardiac life support instruction and were expected to pass it (or pass it in the following year if they failed during this period). The second stage was a refresher and recertification course in advanced cardiac life support at the onset of the third year.

We found that this worked quite well. Our success rates using the American Heart Association criteria ran around 85 to 90 percent in the first year and 100 percent in the third year. This enhanced our residents' credentials in the emergency room.

My experience as a rural physician and as a Navy physician has indicated that anybody doing this type of family practice needs to be absolutely comfortable in handling advanced cardiac life support resuscitation as well as advanced trauma support management until adequate transfer can be made.

My feeling is that the caliber of family practice should be such that any of the faculty members should be willing to and capable of teaching advanced cardiac life support. The article brings attention to the necessity to maintain high levels of clinical competency by the family physician. Advanced cardiac life support is a competence that should be an expected skill of the residency trained family physician.

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Continuity of Care

To the Editor:

Having recently reviewed the continuity of care literature with an emphasis on researchable issues, I was particularly interested in the article by Godkin and Rice (*Relationship of physician continuity to type of health problems in primary care*. *J Fam Pract* 12:99, 1981). The authors focus on provider continu-

ity and suggest an association between chronic illness visits and increased continuity. Unfortunately, the study has serious shortcomings, both methodologically and conceptually.

A number of measurement indices of provider continuity exist currently. The continuity index proposed by the authors would appear to be a crude and unvalidated instrument. By their definition, a patient seen on six visits by three different physicians (continuity index of two) would be presumed to have the same continuity as if he or she had been seen on two occasions by the same physician. Shortell¹ and others²⁻⁴ have provided more sophisticated and sensitive measures of provider continuity. Steinwachs, in the most comprehensive review to date of these measurement techniques, proposes that several indices may be more informative and valuable than one single continuity measure.³

Like many studies in this area, the affect of the setting (a residency training program) on the level of continuity has all but been ignored. Discrepancies already exist in the literature⁵⁻⁷ as to the continuity achieved in the training environment. This fact would imply that provider continuity is influenced significantly by such variables as practice organization and setting, population characteristics (demographic data, health beliefs), and so on.

More importantly, to demonstrate that those with chronic diseases have a higher degree of provider continuity does not permit the assertion that these individuals are more effectively managed by one provider. First, one would have to separate informational continuity (ie, the medical record) from provider continuity. Second, one would

need to have well-defined outcome measures that would be altered by differential continuity levels before making the leap of faith the authors share.

Further studies are most certainly called for to answer these issues so central to the theoretical framework of our burgeoning discipline.

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References

1. Shortell SM: Continuity of medical care: Conceptualization and measurement. *Med Care* 14:377, 1976
2. Bice TW, Boxerman SB: A quantitative measure of continuity of care. *Med Care* 15:347, 1977
3. Steinwachs DM: Measuring provider continuity in ambulatory care: An assessment of alternative approaches. *Med Care* 17:551, 1979
4. Roos LL, Roos NP, Gilbert P, et al: Continuity of care: Does it contribute to quality of care? *Med Care* 18:174, 1980
5. Sloane PD: The effect of relocation of a family practice center on one resident's experience in continuity of care. *J Fam Pract* 9:467, 1979
6. Breslau N, Reeb KG: Continuity of care in a university-based practice. *J Med Educ* 50:965, 1975
7. Rogers J, Curtis P: The achievement of continuity of care in a primary care training program. *Am J Public Health* 70:528, 1980

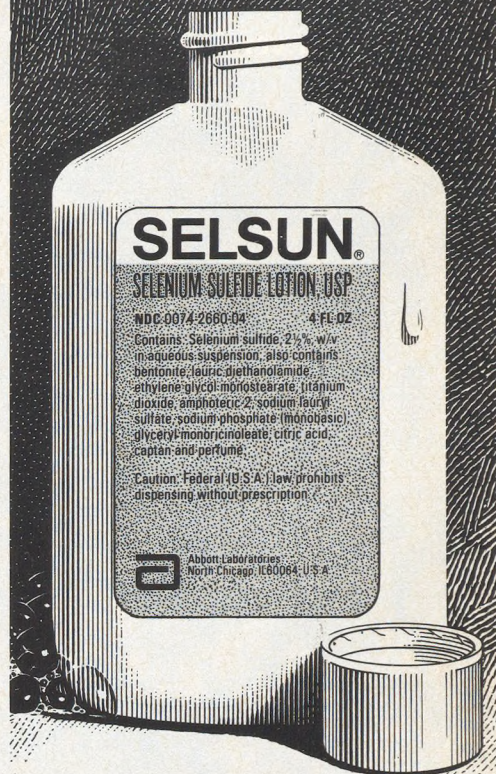
The preceding letter was referred to Dr. Godkin and Ms. Rice, who respond as follows:

We would like to take this opportunity to respond to the critique by Dr. Wall of our recently published article.

In a recent unpublished study the Continuity Index (CI) has been shown to be a valid measure of physician continuity. Physician continuity was compared between a

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Mycelex[®] (clotrimazole)1% Cream
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Indications: Mycelex Cream and Solution are indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, and *Microsporum canis*; candidiasis due to *Candida albicans*; and tinea versicolor due to *Malassezia furfur*.

Contraindications: Mycelex Cream and Solution are contraindicated in individuals who have shown hypersensitivity to any of their components.

Warnings: Mycelex Cream and Solution are not for ophthalmic use.

Precautions: In the first trimester of pregnancy, Mycelex should be used only when considered essential to the welfare of the patient.

If irritation or sensitivity develops with the use of Mycelex, treatment should be discontinued and appropriate therapy instituted.

Adverse Reactions: The following adverse reactions have been reported in connection with the use of this product: erythema, stinging, blistering, peeling, edema, pruritus, urticaria, and general irritation of the skin.

Dosage and Administration: Gently massage sufficient Mycelex Cream or Solution into the affected and surrounding skin areas twice a day, in the morning and evening.

Clinical improvement, with relief of pruritus, usually occurs within the first week of treatment. If a patient shows no clinical improvement after four weeks of treatment with Mycelex, the diagnosis should be reviewed.

How Supplied: Mycelex Cream 1% is supplied in 15 g and 30 g tubes, and 90 g package (2 x 45 g tube).

Mycelex Solution 1% is supplied in 10 ml and 30 ml plastic bottles.

Store between 35° and 86°F.

References: 1. Spiekermann PH, Young MD: Clinical evaluation of clotrimazole: A broad-spectrum antifungal agent. *Arch Dermatol* 112:350-352, 1976. 2. Duhm B, et al: The pharmacokinetics of clotrimazole ¹⁴C. *Postgrad Med J*, July suppl, 1974, pp 13-16.

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nonresidency setting and three residency training sites using the CI and two previously developed measures.^{1,2} Each measure demonstrated a similarly higher degree of continuity in the nonresidency setting. We agree with Dr. Wall that valid comparisons of continuity between different sites are difficult to achieve because of variations in practice organization or catchment populations, ie, factors that will influence continuity. It is for this reason that we would like to suggest that continuity indices are most appropriately used by clinicians in practice (not researchers) for internal management purposes. Thus any index must be simple and calculated easily. One of the major problems with the aforementioned indices is their more complicated mode of calculation and, in one case,¹ difficulty of interpretation. The COC¹ (Continuity of Care) and SECON² (Sequential nature of provider Continuity) indices, for example, both require more detailed data collection than the CI.

Dr. Wall points out, correctly, that the CI cannot differentiate between six visits to three physicians and two visits to one physician. It must be remembered, however, that other sophisticated continuity indices have similar problems. For example, the COC index does not differentiate between sixteen visits to one physician and two visits to one physician, nor does it differentiate between sixteen visits to sixteen physicians and two visits to two physicians. An argument could be made, I guess, that differentiation is not appropriate, since the first example represents perfect continuity in the two situations and the second example reflects perfect discontinuity. A case could be made

just as easily, however, which would suggest that, given the differences in numbers of visits in each pair of situations, there are considerable differences in the degree of continuity. Even so, it should be noted that using the COC, eight visits to five physicians is considered a lesser degree of continuity than four visits to three physicians, a result of questionable validity.

The major point to be drawn from these examples is that continuity indices are most appropriately applied to a whole practice population or a particular sample making an equal number of visits to the same number of physicians. It is very difficult and somewhat arbitrary to interpret differences in continuity between couplets representing different "visits made/physicians encountered" ratios. This is especially the case in the aforementioned examples and others that could be suggested.

Finally, we did not assert that a higher level of continuity is more appropriate or necessary for treating chronic illnesses. Rather, we say that if the above premise is valid (and intuitively it makes some sense), then the distribution of provider resources in the study sites is probably appropriate.

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References

1. Bice TW, Boxerman SB: A quantitative measure of continuity of care. *Med Care* 15:347, 1977
2. Steinwachs DM: Measuring provider continuity in ambulatory care: An assessment of alternative approaches. *Med Care* 17:551, 1979



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