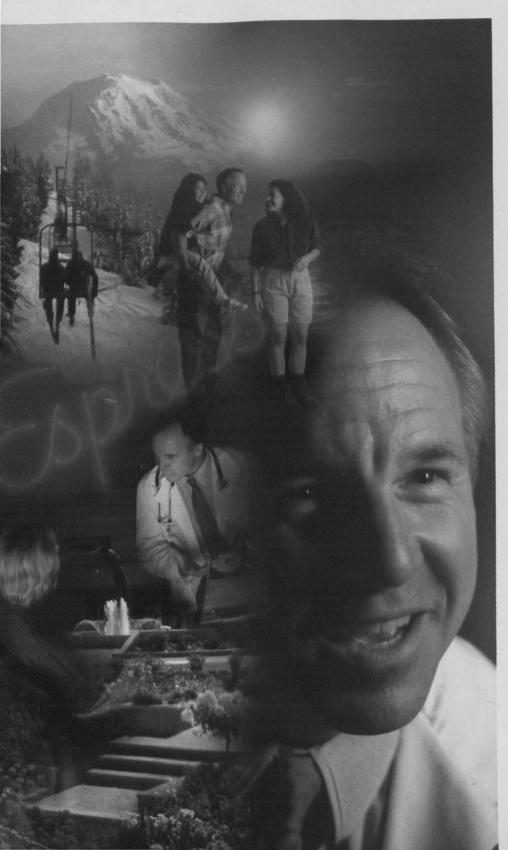
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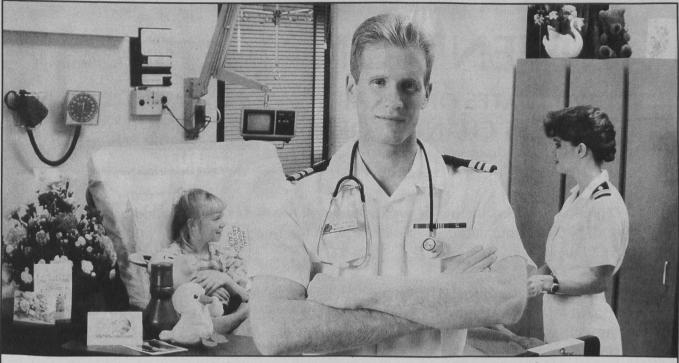
- Requirements for residency training
- Requirements for certification
- Requirements for recertification
- Requirements for Certificates of Added Qualifications in Geriatric Medicine and Sports Medicine
- Future examination dates
- Information on ABFP publications including the *Journal of the American Board of Family Practice*, the *Directory of Diplomates*, and ABFP Reference Guides
- A listing of current and past members of the ABFP Board of Directors
- A staff listing and telephone directory
- The meaning of the ABFP emblem
- Official definitions and policies
- A brief history of the specialty
- Access by city and state to names of ABFP-Certified Family Physicians
- Access by city and state to names of ABFP-Certified Family Physicians with a Certificate of Added Qualifications in Geriatric Medicine
- Access by city and state to names of ABFP-Certified Family Physicians with a Certificate of Added Qualifications in Sports Medicine

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Current addresses for all Diplomates are necessary for communication from the Board relating to the Examinations, updated Recertification information, etc., as well as to ensure the receipt of the *Journal of the American Board of Family Practice.*

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Zip Code		Zip Code		
Year of Certificati	on or Recertification_			
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For bacterial vaginosis*

Metronidazole vaginal gel) (netronidazole vaginal gel) 0.75% Vaginal Gel

resign Streets eur

- the #1 local therapy¹
- efficacy equal to oral metronidazole²
- minimal side effects
 - -low incidence of GI upset (3.4%)
 - -low incidence of nausea (2.0%)
 - -low incidence of metallic taste (1.7%)
- minimal chance of alcohol interaction
- low incidence of yeast overgrowth (6.1%)

Please see adjacent page for brief summary of prescribing information.

*Bacterial vaginosis formerly known as *Gardnerella* vaginitis, nonspecific vaginitis, Haemophilus vaginitis, anaerobic vaginosis, or *Corynebacterium* vaginitis. MetroGel-Vaginal.

Only 5 Day Therapy

MeiroGel-Vaginal. (metronidazole vaginal gel) 0.75% Vaginal Gel

#1 prescribed local therapy for BV

Efficacy equal to oral metronidazole²

In a direct comparative trial of 100 BV patients, MetroGel-Vaginal Therapy

5 days BID had efficacy rates equal to 7 days of oral metronidazole 500 mg BID.

MetroGel-Vaainal.

(metronidazole vaginal gel) 0.75% Vaginal Gel

FOR INTRAVAGINAL USE ONLY. (NOT FOR OPHTHALIS: DERMAL, OR ORAL USE.) Caution: Federal law prohom

Curatek

Only 5 Day Therapy

A clinical diagnosis of bacterial vaginosis is usually defined by the presence of a homogeneous vaginal discharge that (a) has a pH > 4.5. (b) emits a "fishy" amine odor when mixed with a 10% KOH solution, and (c) contains clue cells on microscopic examination. Gram's stain results consistent with a diagnosis of bacterial vaginosis include (a) markedly reduced or absent Lactobacillus morphology, (b) predominance of Gardnerella morphotype, and (c) absent or few white blood cells. Other pathogens commonly associated with vulvovaginitis, eg, Trichomonas vaginalis, Chlamydia trachomatis, Neisseria gonorrhoeae, Candida albicans, and herpes simplex virus should be ruled out.

Brief Summary Before prescribing please see full prescribing information.

MetroGel-Vaginal. (metronidazole vaginal gel)

0.75% Vaginal Gel

FOR INTRAVAGINAL USE ONLY NOT FOR OPHTHALMIC, DERMAL, OR ORAL USE

DESCRIPTION: METROGEL-VAGINAL is formulated at pH 4.0. Each applicator full contains 37.5 mg of metronidazole

CLINICAL PHARMACOLOGY:

Following a single, intravaginal 5-gram dose of metronidazole vaginal gel to 12 normal subjects, a mean maximum serum metronidazole concentration of 23 n gr/m, was reported. This is approximately 2% of the mean maximum serum metronidazole concentration reported in the same subjects administered a single, oral 500-mg dose of metronidazole

INDICATIONS AND USAGE:

METROGEL-VAGINAL is indicated in the treatment of bacterial vaginosis (formerly referred to as *Haemophilus* vaginitis, *Gardnerella* vaginitis, non-specific vaginitis, *Corynebacterium* vaginitis or anaerobic vaginosis). NOTE:

NOTE: For purposes of this indication, a clinical diagnosis of bacterial vaginosis is usually defined by the presence of a homogeneous vaginal discharge that (a) has a pH of greater than 4.5, (b) emits a "fishy" amine dor when mixed with a 10% KOH solution and (c) contains clue cells on microscopic examination. Gram's stain results consistent with a diagnosis of bacterial vaginosis include (a) markedly reduced or absent *Lactobacillus* morphology, (b) predominance of *Gardnesella* morpholyne and (c) observed to for white hold cells of Gardnerella morphotype and (c) absent or few white blood cells.

Other pathogens commonly associated with vulvovaginitis, e.g., Trichomonas vaginalis, Chlamydia trachomatis, N. gonorrhoeae, Candida albicans and Herpes simplex virus should be ruled out.

CONTRAINDICATIONS: METROGEL-VAGINAL is contraindicated in patients with a prior history of hypersensitivity to metronidazole, parabens, other ingredients of the formu-lation or other nitroimidazole derivatives.

WARNINGS:

3M

Convulsive Seizures and Peripheral Neuropathy: Convulsive seizures and peripheral neuropathy, the latter characterized mainly by numbness or paresthesia of an extremity, have been reported in patients treated with oral metronidazole. The appearance of abnormal neurologic signs demands the prompt discontinuation of metronidazole vaginal gel therapy. Metronidazole vaginal gel should be administered with caution to patients with central nervous system diseases

Psychotic Reactions: Psychotic reactions have been reported in alcoholic patients who were using oral metronidazole and disulfiram concurrently. Metronidazole vaginal gel should not be administered to patients who have taken disulfiram within the last two weeks.

PRECAUTIONS:

General: Patients with severe hepatic disease metabolize metronidazole slowly. Accordingly, for such patients, metronidazole vaginal gel should be administered cautiously. Known or previously unrecognized vaginal candidi-asis may present more prominent symptoms during therapy with metronidazole vaginal gel.

Disulfiram-like reaction to alcohol has been reported with oral metronidazole, thus the possibility of such a reaction occurring while on metronidazole vaginal gel therapy cannot be excluded. METROGEL-VAGINAL contains ingredients that may cause burning and irritation of the ey

Drug Interactions: Oral metronidazole has been reported to potentiate the anticoagulant effect of warfarin and other coumarin anticoagulants, resulting in a prolongation of prothrombin tim

Drug/Laboratory Test Interactions: Metronidazole may interfere with cer-tain types of determinations of serum chemistry values, such as aspartate aminotransferase (AST, SGOT) alanine aminotransferase (ALT, SGPT) lactate dehydrogenase (LDH), triglycerides, and glucose hexokina zero may be observed. Valu

Carcinogenesis, Mutagenesis, Impairment of Fertility: Metronidazole has shown evidence of carcinogenic activity in a number of studies involving chronic, oral administration in mice and rats but not in studies involving haminvolving sters. These studies have not been conducted with 0.75% metronidazole vaginal gel, which would result in significantly lower systemic blood levels than those obtained with oral formulations.

Although metronidazole has shown mutagenic activity in a number of in vitro assay systems, studies in mammals (in vivo) have failed to demonstrate a potential for genetic damage.

Fertility studies have been performed in mice up to six times the recom mended human vaginal dose (based on mg/m2) and have revealed no evidence of impaired fertility.

Pregnancy: Teratogenic Effects Pregnancy Category B There has been no experience to date with the use of METROGEL-VAGINAL in pregnant patients. Metronidazole crosses the placental barrier and enters when metronidazole was administered orally to pregnant mice at six times the recommended human vaginal dose (based on mg/m²); however, in a sinthe recommended number vaginal ouse (based on night), however, in a sale gle small study where the drug was administered intraperitoneally, some intrauterine deaths were observed. The relationship of these findings to the drug is unknown. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, and because metronidazole is a carcinogen in rodents, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Specific studies of metronidazole levels in human milk following intravaginally administered metronidazole have not been per-formed. However, metronidazole is secreted in human milk in concentrations similar to those found in plasma following oral administration of metronida-zole. Because of the potential for tumorigenicity shown for metronidazole in mouse and rat studies, a decision should be made whether to discontinue of the metron and discontinue the drug. Taking into account the importance of the metron of the secontinue the drug failed of the second seco nursing or to discontinue the drug, taking into account the importance of the drug to the mother

Pediatric Use: Safety and effectiveness in children have not been stablished

established. ADVERSE REACTIONS: Adverse experiences reported in clinical trials involving 295 patients consid-ered related, probably related or possibly related to METROGEL-VAGINAL were primarily genitourinary and gastrointestinal. Genitourinary reports were vaginal candidiasis (6.1%); vaginal, perineal or vulvar itching (1.4%); urinary frequency, vaginal or vulvar burning or irritation, vaginal discharge (not Candida) and vulvar swelling; each at an incidence of <1%. Gastrointestinal reports were cramps/pain (abdominal/uterine) (3.4%), nausea (2.0%), metal-lic or bad taste (1.7%) and constitution, decreased appetite and diarrhea, each at an incidence of <1%. Increased/decreased white blood cells (1.7%), dizziness, headache, lightheadedness and rash were noted, each at an incidence of <1%.

Other metronidazole formulations: Although lower systemic blood levels Other metronidazole formulations: Although lower systemic blood levels of metronidazole are seen compared to 500 mg of oral metronidazole, the possibility of adverse reactions like those seen with oral metronidazole can-not be excluded presently. Oral metronidazole has produced cardiovascular, central nervous system, gastrointestinal, genitourinary, hematopoietic, hypersensitivity and renal reactions.

DOSAGE AND ADMINISTRATION:

The recommended dose is one applicator full of METROGEL-VAGINAL (approximately 5 grams containing approximately 37.5 mg of metronidazole) intravaginally twice daily for 5 days. The medication should be applied once in the morning and once in the evening.

HOW SUPPLIED:

METROGEL-VAGINAL (metronidazole vaginal gel) is supplied in a 70 gram aluminum tube and packaged with a 5 gram vaginal applicator. NDC number is 55326-200-25.

Caution: Federal law prohibits dispensing without a prescription.

REFERENCES

REFERENCES: MetroGel-Vaginal is prescribed more often than any other intravaginal bac-terial vaginosis therapy. Oct. 1993 through present, National Prescription Audit of 20,000 Retail Pharmacies. IMS America, National Prescription

Audit of 20,000 Retail Fnamacies. IMS America, National Freecingion Audit-NPA. McGregor JA, Hillier SL, Eschenbach DA, Kreutner AK, Galask RP, Efficacy of MetroGel-Vaginal versus oral metronidazole for treatment of bacterial vaginosis. A randomized, single-bilind parallel comparison. Presented at International Society for STD Research; August 1995; New Orleans, LA.

For more information call: 1-800-4BV-NEWS (1-800-428-6397)

1/93

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Each year the American Board of Family Practice (ABFP) publishes and distributes a *Directory of Diplomates* to all current diplomates, a service that has been provided for the past 15 years. Currently, we also provide an abbreviated directory on the World Wide Web.

The ABFP Board of Directors needs to have information about the printed directory's usefulness to the diplomates. Please assist us by responding to this brief survey. You may check the appropriate answers and return the survey as instructed below. Additional comments regarding the directory are welcome.

1.	Have you ever used the printed Directory of Diplomates? (If no, skip to question 3)	□ Yes	□ No	
2.	How often do you use the directory?	□ Weekly □ Quarterly □ Less than ar	☐ Monthly ☐ Annually nnually	
3.	Do you expect to use the World Wide Web as a directory?	☐ Yes	□ No	
4.	Would you be concerned if the printed directory were not distributed to you annually?	☐ Yes	□ No	
Please return this survey via mail or fax to: The American Board of Family Practice Directory Survey 2228 Young Drive Lexington, KY 40504-4294 or Fax: (606) 266-9699				

The Journal of the American Board of Family Practice CLASSIFIED ADVERTISING SECTION

The classified rate is \$1.75 per word (minimum charge of \$75.00 per ad insertion) and \$100.00 per column inch for classified display ads.

Please call (609) 768-9360 and ask for classified advertising rate information on various classified display ad sizes. Prepayment in full is required with all classified advertising.

Confidential reply boxes are an additional \$10.00 per insertion. Responses are sent directly every Tuesday and Thursday, and the box will remain open for three months.

Note: Our classified advertisements are all set in the same typeface and format. Italic, underlining or special typefaces are not available. All ads are listed by geographic location. Classifled advertisements placed with JABFP are restricted to physician recruitment, faculty positions, CME courses, seminars, and practices for sale. All ads must relate to the medical field and are subject to approval.

Please refer to the schedule below for closing

Classified Advertising Deadlines					
Issue Date	Closing Date				
March-April	February 1				
May-June	April 1				
July-August	June 1				
September-October	August 1				
November-December	October 3				

dates. All advertisements for employment must be nondiscriminatory and comply with all applicable laws and regulations. Ads that discriminate against applicants based on sex, age, race, religion, marital status or physical handicap will not be accepted.

Classified advertising orders and correspondence should be directed to:

> Katherine Forelle Advertising Manager MRA Publications, Inc. 2 Greenwich Office Park Greenwich, CT 06831 Tel (203) 629-3550 Fax (203) 629-2536

Northeast

FAMILY PRACTICE—PENNSYLVANIA, Harrisburg area—Join established six physician Family Practice group with 1:5 shared call. Six-figure salary, and excellent benefits. Great area with additional access to Baltimore, Philadelphia, and Lancaster. Contact David Finney, Howe, Lawlor and Associates, at 800-238-7150 or fax CV to 610-974-0574.

NORTHWESTERN NEW JERSEY—Practice opportunities with competitive compensation package available for BE/BC FAMILY PHYSICIANS. Send CV to: Elizabeth Lejeune, Northwest Covenant Medical Center, SSM Ambulatory Care Corporate Offices, 715 Route 10 East, Randolph, NJ 07869. Fax: 201-442-2330. Phone: 201-442-2307.

SUBURBAN PITTSBURGH-FAMILY PRACTICE FACULTY-An excellent opportunity exists for a BC Family Practitioner to become a member of a prestigious faculty group. This fully accredited program, which currently consists of 20 residents, is anticipating expansion. The program is sponsored by a progressive, midsized community hospital noted for its outstanding medical staff. Opportunity to live in a community that provides all of the benefits of a small town and an easy commute to a major metropolitan city. Enjoy award winning school districts, quality affordable housing and a vast array of cultural amenities. Excellent compensation/benefits. For more information, please contact: Elaine Bolanis at Daniel Stern & Associates; The Medical Center East; 211 N. Whitfield Street; Pittsburgh, PA 15206; Call 1-800-438-2476 or FAX 1-800-892-2781.

Southeast

FAMILY PRACTICE FACULTY DEVELOPMENTAL FELLOWSHIP POSITION: The Department of Family and Community Medicine at the University of Missouri-Columbia is accepting applications for positions in our two-year fellowship program to start in July 1997. Since 1980, 42 family physicians have completed fellowship training. Almost all are now in teaching or research positions; many have assumed leadership roles in teaching, research, or administration in family medicine programs. During the first year, the fellowship emphasizes development of knowledge and skills in teaching, critical thinking, original research, patient care, administration, and leadership. During the second year, four areas of concentration are available; clinical teaching, research, geriatrics, and sports medicine. A certificate of added aualification is available in the latter two areas. All fellows earn a master's degree in public health. An optional third year is available. Send or fax your resume to Bernard Ewigman, M.D., MA303 Health Sciences Center, Family and Community Medicine, University of Missouri, School of Medicine, Columbia, Missouri

ASSOCIATE PROGRAM DIRECTOR

training here for 149 years! The Mercy Family Practice Residency is seeking a full-time Associate Director for our newly established 6-6-6 program. We are seeking a partner to join our dynamic and vibrant faculty of 12. Prior residencybased experience is essential. Interests in OB and procedural skills are desirable. Respond to Jesse C. Haggerty, III, MD, MSc, MPH, PhD, The Mercy Hospital of Pittsburgh, Department of Family Practice, 1515 Locust Street, 6th Floor, Pittsburgh, PA 15219. EOE M/F/H/D/V.



65212. Phone: (573) 882-4992, Fax (573) 884-4122. An equal opportunity/affirmative action/ ADA employer.

Midwest

AHEC - FORT SMITH, ARKANSAS is recruiting a family physician for a full-time faculty position. community-based, university-administered 6-6-6 Program in community of 75,000 in scenic Arkansas river valley near Ozark and Ouachita Mountains. Temperate climate with four seasons. Duties include teaching residents and medical students and direct patient care including operative OB. Competitive salary with excellent benefit package. Must be ABFP certified and able to obtain an Arkansas license. Call (501) 785-2431 for Larry L. Hanley, M.D., Program Director or L.C. Price, M.D., AHEC Director, or send CV to 612 So.12th St., Fort Smith, AR 72901-4702. EOE.

EAST CENTRAL ILLINOIS—Exceptional Family Practice opportunity in East Central Illinois. Join four other family physicians in a flourishing practice. New, fully equipped facility, five minutes from Health Center, that serves a patient base of 154,000. Family-friendly call schedule; four and one-half day week. Progressive business environment, strong schools and a small city spirit. Excellent quality of life. Competitive salary and benefits. Call Jackie Laske at (800) 243-4353.

WESTERN WISCONSIN—Join one of our nation¹⁵ largest multispecialty groups with a 35-member Family Practice department. The group now offers Family Practice opportunities in several sulfrounding regional clinics in Western Wiscons¹⁷ and Northern Iowa. Fully equipped facilities. Consultants visit branch sites on a regularly scheduled basis; 92 subspecialists are also easily accessible. These attractive communities are within driving distance of other major urban areas. Excellent quality of life, year-round specta^{C7} ular outdoor recreational opportunities, go¹⁷ geous sightseeing. Attractive salary and benefil package. For more information call Jackie Laske at (800) 243-4353.

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Immediate need for 2 BE/BC FP's to join 4 others and 4 PA's in Alaska's largest multispecialty clinic. We are not going to give you a lot of razzle-dazzle about our clinic except to say, if you want to join a very compatible group of 24 other physicians in a multispecialty clinic and if you have always wanted to come to Alaska, call 907-459-3513 or FAX me your CV at 907-452-2902. Ron Davis, Tanana Valley Clinic, 1001 Noble St., Fairbanks, AK 99701.

West

COLORADO FACULTY POSITION-For 100 years, St. Mary's Hospital and Medical Center, the largest healthcare facility between Denver and Salt Lake City, has provided high quality and progressive care to our community. We're celebrating a century of caring with an even stronger commitment to excellence and a steady focus on the future. Currently, we have a unique opportunity available for a Board Certified Family Practitioner to join our rurally oriented Family Practice Program. This community-based university-affiliated program prides itself on our record of rural placement. Responsibilities include teaching residents and medical students and providing direct patient care including obstetrics. Research experience a plus.

We offer competitive compensation, a flexible benefits package and interview/relocation assistance. Please send CV and statement of interest to: Daniel R. Dill, M.D., Director, St. Mary's Family Practice Residency, 2333 North 6th Street, Grand Junction, CO 81501. EOE

FACULTY POSITION: Family Medicine Spokane, a community-based Family Practice residency affiliated with the University of Washington, seeks a Board Certified FP with 3 years practice including OB. Located in the beautiful Pacific Northwest. Position available July 1, 1997. Full time preferred, part-time considered. Send CV to Gary R. Newkirk, M.D., 104 W. 5th Ave., Suite 200W, Spokane, Washington 99204, (509) 624-2313.

FELLOWSHIP IN RURAL FAMILY MEDICINE Tacoma Family Medicine (TFM) announces openings for August 1, 1997 in our Fellowship in Rural Family Medicine. TFM, an 18-year-old Family Practice Residency affiliated with the University of Washington, has a strong history of training physicians for rural practice. We are currently in the 7th year of our Fellowship in Rural Family Medicine and 5 Fellows are currently participating in the program. It is anticipated that the Rural Fellowship will accept 5 physicians for the year beginning August 1, 1997. The curriculum will consist of 6 months of intensive training in high-risk and operative obstetrics and 6 months of electives tailored to the needs of the individual. Options for the individually tailored time include adult and pediatric critical care, all medical and surgical specialties, emergency services, public health, practice management, etc. As the only civilian residency in Tacoma, WA, located on beautiful Puget Sound, this is an ideal training site. Contact David Acosta, M.D., Program Director, Tacoma Family Medicine, 521 Martin Luther King Jr. Way Street, Tacoma, WA 98405 for details. Applicants should be finishing a Family Practice Residency in 1997 or have previously completed residency training in Family Medicine and have an interest in rural practice.

SEATTLE WASHINGTON—FAMILY MEDICINE COMMUNITY HOSPITAL FAMILY FACULTY POSI-TION—Newly created position open at Providence Hospital Family Practice Residency, an urban-based innercity-focused program whose mission it is to train Family Physicians for service to the underserved and economically disadvantaged in a multicultural, interdisciplinary model. Practice and residency growth necessitates recruitment of an additional faculty person to join the 7.5 FTE faculty at our primary site (6-6-6). This position requires board certification in Family Practice and past experience in practice and/or residency teaching (including obstetrics). We seek a committed, enthusiastic, and energetic new partner to join our faculty group. Salary and benefits are highly competitive. Qualified women and minorities are encouraged to apply. All inquiries are confidential. Address inquiries to: Sam Cullison, MD, Residency Director, Providence Hospital FPR, 550-16th Avenue, Suite 100, Seattle, WA 98122. Or call #206-320-2233 for more information. AA/EEO employer.

Pacific

SOUTHERN CALIFORNIA—Primary Care. We invite you to explore practice opportunities with a prominent, fast-growing healthcare provider seeking primary care physicians for ambulatory centers in the greater Los Angeles area. Must be BE/BC in Family Practice, Internal Medicine or IM-Peds with outstanding clinical skills, experience and/or a desire to work in a managed care environment. Compensation includes competitive salary, bonus, and benefits. Contact: Sharon Tanabe, Korn/Ferry International, (310) 843-4179, FAX CVs to (310) 553-6452.

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FAMILY PRACTITIONERS

We are seeking a BC/BE Family Physician to join our existing family medicine group that is part of a larger multi-specialty group associated with a UCSF Family Practice residency program. Serving the needs of a bilingual (English/ Spanish) community, this group practices comprehensive inpatient and outpatient family medicine, including obstetrics with supportive specialty back-up.

Along with challenging clinical opportunities and a competitive compensation program, our HPSA designation offers the potential for loan repayment. Our highly desirable Salinas location is just 17 miles inland from the Monterey Bay and presents a diverse community of 120,000 with moderate year-round weather. Come share our success! Send your CV with letter of interest to: Medical Staff Office, Natividad Medical Center, 1330 Natividad Road, PO. Box 81611, Salinas, CA 93912-1611, or call (408) 755-4196. AA/EOE/M/F/H.



Family Practice Physicians

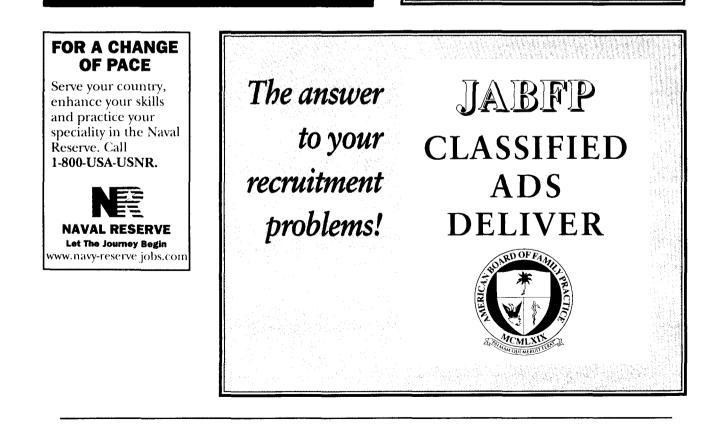
If you're a physician looking for a professional life that keeps you attuned to high-tech medical advances and offers you financial rewards, opportunities for career development and excellent benefits, the Navy Medical Corps may be for you. As a Navy physician, you'll practice in a truly collegial environment, where physicians support each other rather than engage in economic competition. You'll be a commissioned officer and a respected member of the Navy's prestigious health care delivery team.

You'll work in clinical settings in the United States and around the world with top professionals and state-of-the-art equipment and facilities. Through funded continuing medical education and specialty training, you'll have the opportunity to develop your full professional potential as well as the freedom to move from practice to research or teaching without losing seniority, salary level, or retirement benefits.

You'll earn an excellent starting salary based on your ability and experience, and federal law provides free medical liability protection to Navy physicians. You may also be entitled to special pay in addition to your regular salary and allowances. Navy benefits include 30 days of paid vacation earned each year, free medical and dental care, tax-free housing and food allowance, an excellent retirement system and opportunities for free travel to some of the most exotic and beautiful places in the world.

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with 625 mg HCTZ Hardworking therapy patients hardly notice

References: I. DeQuattro V, Weir MR. Bisoprolol fumarate/hydrochlorothiazide 6.25 mg: a new low-dose option for first-line antihypertensive therapy. Adv Ther. 1993;10:197-206. 2. Zachariah PK, Messerli FH, Mroczek W, Low-dose bisoprolol/hydrochlorothiazide: an option in first-line, antihypertensive treatment. *Clin Ther.* 1993;15:779-787. 3. Prisant LM, Weir MR, Papademetriou V, et al. Low-dose drug combination therapy: an alternative first-line approach to hypertension treatment. Am Heart J. 1995;130:359-366, **4.** Data on file. Lederle Laboratories, Pearl River, NY.

Brief Summary

ZIAC® (Bisoprolo) Fumarate and Hydrochlorothiazide) Tablets

FOR FULL PRESCRIBING INFORMATION, PLEASE CONSULT PACKAGE INSERT.

DESCRIPTION

ZIAC (bisoprolol fumarate and hydrochlorothiazide) is indicated for the treatment of hypertension. It combines we antihypertensive agents in a once-daily dosage: a synthetic beta,-selective (cardioselective) adrenoceptor blocking agent (bisoprolol fumarate) and a benzothiadiazine diuretic (hydrochlorothiazide).

CLINICAL PHARMACOLOGY

At doses ≥ 20 mg bisoproloi fumarate inhibits beta, adrenoreceptors located in bronchial and vascular muscu-lature. To retain relative selectivity, it is important to use the lowest effective dose.

CONTRAINDICATIONS

Cardiogenic shock, overt cardiac failure (see WARNINGS), second- or third-degree AV block, marked sinus bradycardia, anuria, and hypersensitivity to either component of this product or to other sulfonamide-derived drugs

WARNINGS

Cardiac Filling: Beta-blocking agents should be avoided in patients with overt congestive failure. Patients Without a History of Cardiac Failure: Continued depression of the myocardium with beta-blockers can precipitate cardiac failure. At the first signs or symptoms of heart failure, discontinuation of ZIAC should be considered.

Abrupt Cessation of Therapy: Abrupt cessation of beta-blockers should be avoided. Even in patients without overt Coronary artery disease, it may be advisable to taper therapy with ZIAC over approximately 1 week with the patient Under careful observation. If withdrawal symptoms occur, beta-blocking agent therapy should be reinstituted, at ist temporarily.

Peripheral Vascular Disease: Beta-blockers should be used with caution in patients with peripheral vascular spastic Disease: PATIENTS WITH BRONCHOSPASTIC PULMONARY DISEASE SHOULD, IN GENERAL

Bronchogastic Disease: PATIENTS WITH BHURCHUSPROTUC FURNISHING FURNESHIES AND A CONTRECTIVE STATEMENTS FOR THE STATEMENT STATEMENT STATEMENT STATEMENTS FOR THE STATEMENT STATEMENT STATEMENT STATEMENTS FOR STATEMENTS AND A STATEMENTS A STATEMENTS A STATEMENT A

Diockage may be rollowed by an exact state of the thiazides may develop in patients with impaired renal function. In such Renal Disease: Cumulative effects of the thiazides may develop in patients with impaired renal function. In such patients, thiazides may precipitate azotemia. In subjects with creatinine clearance less than 40 mL/min, the plasma half-life of bisoprolol furnarate is increased up to threefold, as compared to healthy subjects. **Hepatic Disease:** ZIAC should be used with caution in patients with impaired hepatic function or progressive liver disease.

PRECAUTIONS

PRECAUTIONS General: Electrolyte and Fluid Balance Status: Periodic determination of serum electrolytes should be performed, and patients should be observed for signs of fluid or electrolyte disturbances. Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia. Hypokalemia may develop. Hypokalemia and hypomagnesemia can provoke ventricular arrhythmias or sensi-tize or exaggerate the response of the heart to the toxic effects of digitalis. Dilutional hyponatremia may occur in edematous patients in hot weather, appropriate therapy is water restric-tion rather than sait administration, except in rare instances when the hyponatremia is life-threatening. In actual sait depletion, appropriate replacement is the therapy of choice. Parathyroid Disease: Calcium excretion is decreased by thiazides, and pathologic changes in the parathyroid glands, with hypercalcemia and hypophosphatemia, have been observed in a few patients on prolonged thiazide therapy. Hyporturizemia: Hyperruireemia or acute gout may be precipitated in certain patients receiving thiazide diuretics.

Hyperuricemia: Hyperuricemia or acute gout may be precipitated in certain patients receiving thiazide diuretics. Hyperuricemia: Hyperuricemia or acute gout may be precipitated in certain patients receiving thiazide diuretics. Bisporoiol furmarate, alone or in combination with HCTZ, has been associated with increases in uric acid. Drug Interactions: ZIAC may potentiate the action of other antihypertensive agents used concomitantly. ZIAC should not be combined with other beta-blocking agents. In patients receiving concurrent therapy with clonidine, if therapy is to be discontinued, it is suggested that ZIAC be discontinued for several days before the withdrawal of clonidine.

If the ray is to be discontinued, it is suggested that ZIAC be discontinued for several days before the withdrawal of clonkine. ZIAC should be used with caution when myocardial depressants or inhibitors of AV conduction or antiar-mythmic agents are used concurrently. *Bisoprolol Fumarate:* Concurrent use of ritampin increases the metabolic clearance of bisoprolol fumarate, shortening its elimination half-life. Pharmacokinetic studies document no clinically relevant interactions with other agents given concomitantly, including thiazide diuretics, digoxin and climetidine. There was no effect of bisoprolol fumarate on prothrombin times in patients on stable doses of warfarin. Misoprolor fumarate on prothrombin times in patients on stable doses of warfarin. Misoprolor fumarate on prothrombin times in patients on stable doses of warfarin. Misoprolor fumarate on prothrombin times in patients on stable doses of warfarin. Misoprolor fumarate on prothrombin times in patients on stable doses of warfarin. Misoprolor to the usual doses of epinephrine used to treat allergic reactions. *Mythrochlorothiazide*: The following drugs may interact with thiazide diuretics. Alcohol, barbiturates, or narcot-risc – potentiation of orthostatic hypotension may occur. Dosage adjustment of the antidiabetic drugs (oral agents and insulin) may be required. Other antihypertensive drugs – additive effect or potentiation. Cholestyramine and reduce its absorption in the gastrointestinal tract by up to 85 percent and 43 percent, respectively. Corticosteroids, ACTH intensified electrolyte depletion, particularly hypokalemia. Possible decreased responses to mescle relaxants, nondepolarizing. Generally, lithium stouid not be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add ahigh risk of lithium toxicity. The given with diuretics. Diuretic agents reduce the renal clearance of lithium and add ahigh risk of lithium toxicity. The servicins and possible exceased and anti-inflammatory agent can reduce

Deen reported in patients receiving inactues. The analyses and the post-sympathectomy patient. Laboratory Test Interactions: Based on reports involving thiazides, ZIAC may decrease serum levels of protein-bound iodine without signs of thyroid disturbance. Because it includes a thiazide, ZIAC should be discontinued before carrying out tests for parathyroid function (see **PRECAUTIONS**—*Parathyroid Disease*).

ADVERSE REACTIONS

ADVERSE REACTIONS ZIAC: Bisoproloi fumarate/H6.25 mg is well tolerated in most patients. Most adverse effects (AEs) have been mild and transient. In more than 65,000 patients treated worldwide with bisoproloi fumarate, occurrences of broncho-spasm have been rare. Discontinuation rates for AEs were similar for B/H6.25 mg and placebo-treated patients. In the United States, 252 patients received bisoproloi fumarate (2.5, 5, 10, or 40 mg)/H6.25 mg and 144 patients received placebo in two controlled trials. In Study 1, bisoproloi fumarate 5/H6.25 mg was administered for 4 weeks. In Study 2, bisoproloi fumarate 2.5, 10 or 40/H6.25 mg was administered for 12 weeks. All adverse experiences, whether drug-related or on tot, and drug-related adverse experiences in patients treated with B2.5-10/H6.25 mg, reported during comparable, 4 week treatment periods by at least 2% of bisoproloi fumarate/ H6.25 mg-treated patients (plus additional selected adverse experiences) are presented in the following table:

ZIAC® (Bisoproloi Fumarate and Hydrochlorothiazide) Tablets

% of Patients with Adverse Experiences*							
Body System/ Adverse Experience	All Adverse Experiences			- Drug-Related Adverse Experiences			
	Placebot	B2.5-40/H6.25*	Placebo*	B2.5-10/H6.25*			
	(n = 144) %	(n = 252) %	(n = 144) %	(n = 221) %			
Cardiovascular							
bradycardia	0.7	1.1	0.7	0.9			
arrhythmia	1.4	0.4	0.0	0.0			
peripheral ischemia	0.9	0.7	0.9	0.4			
chest pain	0.7	1.8	0.7	0.9			
Respiratory							
bronchospasm	0.0	0.0	0.0	0.0			
cough	1.0	2.2	0.7	1.5			
rhinitis	2.0	0.7	0.7	0.9			
URI	2.3	· 2.1	0.0	0.0			
Body as a Whole			• -				
asthenia	0.0	0.0	0.0	0.0			
fatigue	2.7	4.6 1.1	1.7	3.0			
peripheral edema	0.7	1.1	0.7	0.9			
Central Nervous System dizziness	1.0	5.1	1.0				
headache	1.8 4.7	4.5	1.8 2.7	3.2			
Musculoskeletal	4./	4.0	2.1	0.4			
muscle cramps	0.7	1.2	0.7	1.1			
myalgia	1.4	2.4	0.0	0.0			
Psychiatric	1.4	2.4	0.0	0.0			
insomnia	2.4	1.1	2.0	1.2			
somnolence	0.7	1.1	0.7	0.9			
loss of libido	12	0.4	1.2	0.4			
impotence	1.2 0.7	1.1	0.7	1.1			
Gastrointestinal				•••			
diarrhea	1.4	4.3	1.2	1.1			
nausea	0.9	1.1	0.9	0.9			
dyspepsia	0.9 0.7	1.2	0.7	0.9			
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Averages adjusted to combine across studies. Combined across studies.

Combined across studies. Other adverse experiences that have been reported with the individual components are listed below. Bisoproiol Fumarate: In clinical trials worldwide, a variety of other AEs, in addition to those listed above, have been reported. While in many cases it is not known whether a causal relationship exists between bisoproiol and these AEs. they are listed to alert the physical to a possible relationship. Central Averues System: Unsteadiness, vertigo, syncope, paresthesia, hyperesthesia, sleep disturbance/vivid dreams, depression, anxiety/restlessness, decreased concentration/memory. *Cardiovascular:* Palpitations and other thytim disturbances, cold extremities, claudication, hypotension, orthostatic hypotension, chest pain, congestive heart failure. Gastrointestinaf: Gas-tric/epigastric/abdominal pain, peptic ulcer, gastritis, vomiting, constipation, dry mouth. *Musculoskeletali*: Arthraigia, muscle/ioint pain, back/neck pain, twitching/aremor, Skin: Rash, acne, eczema, psoriasis, skin irrita-tion, pruritus, purpura, flushing, sweating, alopecia, dermatitis, exfoliative dermatitis (very rarely), cutaneous vasculitis. *Special Senses:* Visual disturbances, coular pain/pressure, abnormal lacrimation, tinnitus, decreased hearing, earache, taste abnormalities. *Metabolic:* Gout. *Respiratory:* Asthma, bronchitis, dyspnea, pharyngitis, sinusitis. *Genitourinary:* Peyronite disease (very rarely), cysitis, renal colic, polyuria. *General:* Malaise, edema, weight gain, angioedema.

In addition, a variety Peyronie's disease (very rarely), cystitis, renal colic, polyuria. General: Malaise, edema, weight gain, angioedema. In addition, a variety of adverse effects have been reported with other beta-adrenergic blocking agents and should be considered potential adverse effects: *Central Nervous System*: Reversible mental depression progress-ing to catatonia, hallucinations, an acute reversible syndrome characterized by disorientation to time and place, emotional lability, slightly ciouded sensorium. *Allergic:* Fever, combined with aching and sore throat, laryngo-spasm, and respiratory distress. *Hematologic*: Agranulocytosis, thrombocytopenia. *Gastrointestinal:* Mesenteric arterial thrombosis and ischemic colitis. *Miscellaneous*: The oculomucocutaneous syndrome associated with the beta-blocker practoiol has not been reported with bisoprolol lumarate during investigational use or extensive foreign marketing experience. *Hydrochlorothiazide*: The following adverse experiences, in addition to those listed in the above table, have been reported with hydrochlorothiazide (generally with doses of 25 mg or greater). *General:* Weakness. *Central Ner-vous System:* Vertigo, paresthesia, restlessness. *Cardivascular:* Orthostatic/hypotension (may be potentiated by alcohol, bartiturates, or narotics). *Gastrointestinal:* Anorexia, gastri: irritation, cramping, constipation, jaun-dice (intrahepatic cholestatic jaundice), pancreatitis, cholecystitis, sialadenitis, dry mouth. *Musculoskeletati:* Muscle spasm. *Hypersensitive Reactions:* Purpura, photosensitivity, rash, uritorian, necrotizing anguistis (vascu-litis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary edema, anaphy-lactic reactions. *Special Senses:* Transient blurred vision, xanthopsia. *Metabolic:* Gout. *Genitourinary:* Sexual dysfunction, renal failure, renal dysfunction, interstitial nephritis.

LABORATORY ABNORMALITIES

214C: Because of the low does of hydrochlorothiazide in ZIAC, adverse metabolic effects with B/H6.25 mg are less frequent and of smaller magnitude than with HCTZ 25 mg. Treatment with both beta-blockers and thiazide diuretics is associated with increases in uric acid. Mean increases in serum triglycerides were observed in patients treated with bisoproloi fumarate and hydro-chlorothiazide 6.25 mg. Total cholesterol was generally unaffected, but small decreases in HDL cholesterol were noted. were noted.

Were noted. Other laboratory abnormalities that have been reported with the individual components are listed below. **Bisoprolol Fumarate**: In clinical trials, the most frequently reported laboratory change was an increase in serum triglycerides, but this was not a consistent finding. Sporadic liver test abnormalities have been reported. In the U.S. controlled trials experience with bisoprolol fumarate treatment for 4 to 12 weeks, the incidence of concomitant elevations in SGOT and SGPT of between 1 to 2 times normal was 3.9%, compared to 2.5% for placebo. No patient had concomitant elevations greater than twice normal

In the long-term, uncontrolled experience with bisoproiol fumarate treatment for 6 to 18 months, the incidence of one or more concomitant elevations in SGOT and SGPT of between 1-2 times normal was 6.2%. The incidence of multiple occurrence was 1.9%. For concomitant elevations in SGOT and SGPT of greater than twice normal, the incidence was 1.5%. The incidence of multiple occurrences was 0.3%. In many cases these elevations were attributed to undertying disorders, or resolved during continued treatment with bisoproloi fumarate. Other laboratory changes included small increases in uric acid, creatinine, BUN, serum potassium, glucose, and phosphorus and decreases in WBC and platelets. There have been occasional reports of eosinophilia. These were generally not of clinical importance and rarely resulted in discontinuation of bisoproloi fumarate. As with other beta-blockers, ANA conversions have also been reported on bisoproloi fumarate. As with other beta-blockers, ANA conversions have also been reported on bisoproloi fumarate. As with other beta-blockers, ANA conversions have also been reported on bisoproloi fumarate. As with other beta-blockers, ANA conversions have also been reported on bisoproloi fumarate. As with other beta-blockers, ANA conversions have also been reported on bisoproloi fumarate. As outper-term studies converted to a positive titre, although about one-third of these patients subsequently reconverted to a negative titer while on continued therapy. Hydrochlorothiazide: Hyperglycemia, glycosuria, hyperuicemia, hypokalemia and other electrolyte imbalances (see **PRECAUTIONS**), hypercalcemia, leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia, and hemolytic anemia have been associated with HCT therapy. See **DOSAGE AND ADMINISTRATION** section in package insert for complete dosing and precautionary information.



FOERLE LABORATORIES DIVISION American Cyanamid Company Pearl River, NY 10965

REV. 11/94 L-41535-94

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