

MONISTAT* Dual-Pak*

Suppositories/Cream

MONISTAT* 3 Vaginal Suppositories

(miconazole nitrate 200 mg)

MONISTAT-DERM* Cream

(miconazole nitrate 2%)

INDICATIONS AND USAGE: MONISTAT 3 Vaginal Suppositories are indicated for the local treatment of vulvovaginal candidiasis (moniliasis). Effectiveness in pregnancy or in diabetic patients has not been established.

MONISTAT-DERM Cream—For topical application in the treatment of cutaneous candidiasis (moniliasis).

CONTRAINDICATIONS: MONISTAT 3 Vaginal Suppositories—Patients known to be hypersensitive to the drug.

MONISTAT-DERM Cream has no known contraindications.

PRECAUTIONS: MONISTAT 3 Vaginal Suppositories—General: Discontinue drug if sensitization or irritation is reported during use. The base contained in the suppository formulation may interact with certain latex products, such as that used in vaginal contraceptive diaphragms. Concurrent use is not recommended.

Laboratory Tests: If there is a lack of response to MONISTAT 3 Vaginal Suppositories, appropriate microbiological studies (standard KOH smear and/or cultures) should be repeated to confirm the diagnosis and rule out other pathogens.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies to determine carcinogenic potential have not been performed.

Fertility (Reproduction): Oral administration of miconazole nitrate in rats has been reported to produce prolonged gestation. However, this effect was not observed in oral rabbit studies. In addition, signs of fetal and embryo toxicity were reported in rat and rabbit studies, and dystocia was reported in rat studies after oral doses at and above 80 mg/kg. Intravaginal administration did not produce these effects in rats.

Pregnancy: Since imidazoles are absorbed in small amounts from the human vagina, they should not be used in the first trimester of pregnancy unless the physician considers it essential to the welfare of the patient.

Clinical studies, during which miconazole nitrate vaginal cream and suppositories were used for up to 14 days, were reported to include 514 pregnant patients. Follow-up reports available in 471 of these patients reveal no adverse effects or complications attributable to miconazole nitrate therapy in infants born to these women.

Nursing Mothers: It is not known whether miconazole nitrate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when miconazole nitrate is administered to a nursing woman.

MONISTAT-DERM Cream—If a reaction suggesting sensitivity or chemical irritation should occur, use of the medication should be discontinued. For external use only. Avoid introduction of MONISTAT-DERM Cream into the eyes.

ADVERSE REACTIONS: MONISTAT 3 Vaginal Suppositories—During clinical studies with the MONISTAT 3 Vaginal Suppository (miconazole nitrate, 200 mg) 301 patients were treated. The incidence of vulvovaginal burning, itching or irritation was 2%. Complaints of cramping (2%) and headaches (1.3%) were also reported. Other complaints (hives, skin rash) occurred with less than a 0.5% incidence. The therapy-related dropout rate was 0.3%.

MONISTAT-DERM Cream—There have been isolated reports of irritation, burning, maceration, and allergic contact dermatitis associated with application of MONISTAT-DERM.

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.

GATEKEEPERS IN PRIMARY CARE

To The Editor:

The article authored by Drs. Bertakis and Robbins (*Bertakis KD, Robbins JA: Gatekeeping in Primary Care: A Comparison of Internal Medicine and Family Practice. J Fam Prac 1987; 24:306-309*) would be more properly titled without the word "Gatekeeping."

Gatekeeper¹ is a buzzword that should be used precisely. The word refers to the specific function of a patient's chosen or assigned primary care physician in a prepaid health plan. The gatekeepers "... must approve all care provided to their patients. This approval is a condition of payment for the service. . . ."²

I have heard this word used as a pejorative term by both patients and physicians in our area. "Case manager" is a phrase that really describes this function and does not generally carry such an emotional connotation as gatekeeper.

The study does give an interesting view of how family practice residents compare with internal medicine residents within a training program. The study may also reflect (1) what tests or referrals the respective attending physicians suggested to the residents when asked for advice, (2) a cost-effective approach to medicine taught and modeled by family medicine faculty, and (3) feedback on test use,³ referrals, and hospital care given to family practice residents by their department's faculty members.

The residency training period is a time when consultant physicians should be utilized more readily than later in private practice; consultants are an important source of teaching. Laboratory tests also may be ordered

a bit more freely in residency than in private practice. By actually using the test, the resident learns what the test can and cannot do and sees to what extent the result can add to the history and physical examination.

It is important to teach residents cost-effective medical treatment. However, we do not want to confuse them by pushing this too hard, too early. It is best at the beginning to expose residents to the concept that, "in the practice of medicine, physicians are all obligated to do all they can for their patients without regard to any costs to society."⁴ After that, they can decide whether they wish to assume the role of a "gatekeeper."

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References

1. Moore S: Cost containment through risk-sharing by primary care physicians. *N Engl J Med* 1979; 300:1359-1363
2. Eisenberg JM: The internist as gatekeeper: Preparing the general internist for a new role. *Ann Intern Med* 1985; 102:537
3. Berwick DM, Coitin KL: Feedback reduces test use in a health maintenance organization. *JAMA* 1986; 255:1450-1454
4. Levinsky NG: The doctor's master. *N Engl J Med* 1984; 311:1573-1575

PERINATAL OUTCOMES AND FAMILY MEDICINE

To the Editor:

Rosenblatt's editorial¹ and the articles by Franks and Eisinger² and Mengel and Phillips³ will contribute to the literature needed to support the

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*Monistat
Dual-Pak*

ORTHO PHARMACEUTICAL CORPORATION
Raritan, New Jersey 08869



*Trademark

NIX FOR LICE®

CREME RINSE

permethrin 1%

PEDICULICIDAL/OVICIDAL ACTIVITIES: *In vitro* data indicate that permethrin has pediculicidal and ovicidal activity against *Pediculus humanus var. capitis*. The high cure rate (97-99%) of Nix in patients with head lice demonstrated at 14 days following a single application is attributable to a combination of its pediculicidal and ovicidal activities and its residual persistence on the hair which may also prevent reinfestation.

INDICATIONS AND USAGE: Nix is indicated for the single-application treatment of infestation with *Pediculus humanus var. capitis* (the head louse) and its nits (eggs). Retreatment for recurrences is required in less than 1% of patients since the ovicidal activity may be supplemented by residual persistence in the hair. If live lice are observed after at least seven days following the initial application, a second application can be given.

CONTRAINDICATIONS: Nix is contraindicated in patients with known hypersensitivity to any of its components, to any synthetic pyrethroid or pyrethrin, or to chrysanthemums.

WARNING: If hypersensitivity to Nix occurs, discontinue use.

PRECAUTIONS:

General: Head lice infestation is often accompanied by pruritus, erythema, and edema. Treatment with Nix may temporarily exacerbate these conditions.

Information for Patients: Patients with head lice should be advised that itching, redness, or swelling of the scalp may occur after application of Nix. If irritation persists, they should consult their physician. Nix is not irritating to the eyes; however, patients should be advised to avoid contact with eyes during application and to flush with water immediately if Nix gets in the eyes. In order to prevent accidental ingestion by children, the remaining contents of Nix should be discarded after use.

Combing of nits following treatment with Nix is not necessary for effective treatment. However, patients may do so for cosmetic or other reasons. The nits are easily combed from the hair treated with Nix after drying.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Six carcinogenicity bioassays were evaluated with permethrin, three each in rats and mice. No tumorigenicity was seen in the rat studies. However, species-specific increases in pulmonary adenomas, a common benign tumor of mice of high spontaneous background incidence, were seen in the three mouse studies. In one of these studies there was an increased incidence of pulmonary alveolar-cell carcinomas and benign liver adenomas only in female mice when permethrin was given in their food at a concentration of 5000 ppm. Mutagenicity assays, which give useful correlative data for interpreting results from carcinogenicity bioassays in rodents, were negative. Permethrin showed no evidence of mutagenic potential in a battery of *in vitro* and *in vivo* genetic toxicity studies.

Permethrin did not have any adverse effect on reproductive function at a dose of 180 mg/kg/day orally in a three-generation rat study.

Pregnancy: Teratogenic Effects: Pregnancy Category B: Reproduction studies have been performed in mice, rats, and rabbits (200-400 mg/kg/day orally) and have revealed no evidence of impaired fertility or harm to the fetus due to permethrin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the evidence for tumorigenic potential of permethrin in animal studies, consideration should be given to discontinuing nursing temporarily or withholding the drug while the mother is nursing.

Pediatric Use: Nix is safe and effective in children two years of age and older. Safety and effectiveness in children less than two years of age have not been established.

ADVERSE REACTIONS: The most frequent adverse reaction to Nix is pruritus. This is usually a consequence of head lice infestation itself, but may be temporarily aggravated following treatment with Nix. 5.9% of patients in clinical studies experienced mild transient itching; 3.4% experienced mild transient burning/stinging, tingling, numbness, or scalp discomfort; and 2.1% experienced mild transient erythema, edema, or rash of the scalp.

DOSAGE AND ADMINISTRATION:

Adults and Children: Nix is intended for use after the hair has been washed with shampoo, rinsed with water and towel dried. Apply a sufficient volume of Nix to saturate the hair and scalp. Nix should remain on the hair for 10 minutes before being rinsed off with water. A single treatment is sufficient to eliminate head lice infestation. Combing of nits is not required for therapeutic efficacy, but may be done for cosmetic or other reasons.

SHAKE WELL BEFORE USING.


HOW SUPPLIED: Nix (Permethrin) 1% (wt./wt.) Creme Rinse is supplied in plastic squeeze bottles that contain 2 fl. oz. weighing 56 g. (NDC-0081-0780-81)

Store at 15°-25°C (59°-77°F).

Reference: 1. Data on file, Burroughs Wellcome Co.

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 Burroughs Wellcome Co.
Research Triangle Park
North Carolina 27709

LETTERS TO THE EDITOR

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role of family physicians in obstetric care and research. I have a concern, however, with the editorial. I suspect that most family physicians will take exception to Rosenblatt's statement that "Family medicine [is] a medical specialty built more on [a] social role than on anatomical or technological expertise. . . ." If, however, he believes this dictum, why did he ignore the psychosocial role of the family physician as an assessor and intervenor in facilitating positive pregnancy outcomes? The measurement of psychosocial risk factors in pregnancy outcome has been a part of medical literature for 30 years.⁴ The recent contributions from family medicine centers at the University of Oklahoma,⁵ Case Western Reserve University,⁶ and the University of Washington,^{7,8} attest to the significance of the contributions of psychosocial risk to pregnancy outcome. It is unfortunate that *The Journal* editorial on adverse perinatal outcomes did not give recognition to these contributions.

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References

1. Rosenblatt RA: Perinatal outcomes and family medicine: Refocusing the research agenda. *J Fam Pract* 1987; 24:119-122
2. Franks P, Eisinger S: Adverse perinatal outcomes: Is physician specialty a risk factor? *J Fam Pract* 1987; 24:152-156
3. Mengel MB, Phillips WR: The quality of obstetric care in family practice: Are family physicians as safe as obstetricians? *J Fam Pract* 1987; 24:159-164
4. Wasser SK, Isenberg DY: Reproductive failure among women: Pathology or adaptation? *J Psychosom Obstet Gynaecol* 1986; 5:153-175
5. Ramsey CN Jr, Abell TD, Baker LC: The relationship between family functioning, life events, family structure, and the outcome of pregnancy. *J Fam Pract* 1986; 22:521-527
6. Reeb KG, Graham AV, Zyzanski SJ, Kitson GC: Predicting low birth weight and complicated labor in urban black women: A biopsychosocial perspective. Presented at Society of Teachers of Family Medicine,

Section on Family, Amelia Island, North Carolina, March 8, 1986

7. Smilkstein G, Helsper-Lucas A, Ashworth C, et al: Prediction of pregnancy complications: An application of the biopsychosocial model. *Soc Sci Med* 1984; 18:315-321
8. Pagel M, Smilkstein G, Regan H: Social and psychological influences on pregnancy outcomes: A controlled prospective study. Presented at Society of Teachers of Family Medicine, Section on Family, Amelia Island, North Carolina, March 8, 1986

FLEXIBLE SIGMOIDOSCOPY

To the Editor:

In "A Critical Review of Adult Health Maintenance: Part 3. Prevention of Cancer" (*J Fam Pract* 1986; 22:511-530), Frame notes that patient acceptance of screening sigmoidoscopy has been a major problem. I would contend that poor compliance with sigmoidoscopy by patients can be modified significantly by the family physician.

Since 1979 I have been performing 60-cm left colon examinations. Year by year patient acceptance improves. Currently the return on examinations is 10 to 15 percent positive for polyps, of which about one third are villous adenomas.

With regard to cost, the flexible sigmoidoscope examination approximates the mammogram. My patients seem to accept the examination after a careful explanation of health-risk appraisal.

Performing the examination is an art. Careful physician awareness of the patient's comfort level and judicious use of glucagon or Versed allows good patient-to-patient reporting of the experience with the examination.

Since colon cancer does have significant morbidity, and since early diagnosis usually allows detection of less-advanced disease, the family physician is providing a caring and beneficial service by encouraging and professionally performing flexible left colon examinations.

Leon J. Davis, MD
Thermopolis, Wyoming

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SPECIALTY AND PERINATAL OUTCOMES

To the Editor:

The article "Adverse Perinatal Outcomes: Is Physicians' Specialty a Risk Factor?" by Franks and Eisinger (*Franks P, Eisinger S: J Fam Pract 1987; 24:152-156*) raises questions about the samples of both family physicians and obstetricians' practices. Approximately 25 percent of both practices had fewer than four visits. There is no mention as to whether the obstetric practices also involved an obstetric clinic at Highland Hospital, which might explain this low number of visits. It is unusual for a private practice of obstetricians and even for a family practice residency model unit to have that high percentage of extremely late registrants for care.

It was noted that none of the 73 in the random sample assigned to obstetricians had prenatal bleeding, and only two of the 73 patients assigned to family physicians had prenatal bleeding. I also questioned these figures. My best guess would be that this represents poor record keeping or wishful thinking.

Joel Potash, MD
Department of Family Practice
Health Science Center
State University of New York
Syracuse

The preceding letter was referred to Dr. Franks, who responds as follows:

Dr. Potash correctly notes an apparently high rate of late registration for care and low rate of prenatal bleeding. It was not made explicit in the original report that the chart review was based on the hospital records. It is hospital policy to request a prenatal chart, on which some of this data were based, at 36 weeks' gestation. Thus, the apparently high percentage of late registration probably reflects an artifact of visits in the last month of pregnancy not being re-

corded. The chart review represented a random sample of over 6,000 deliveries, and it is possible that some obstetric clinic patients were included. However, the obstetric clinic accounts for a very small percentage of the deliveries at Highland Hospital and thus is an unlikely source for bias. In general, for a potential source of bias to actually confound results, it is necessary for that variable to operate differently on patients or charts of family physician providers than on those of obstetrician providers. There is no serious evidence that this might be the case.

Peter Franks, MD
Family Medicine Program
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DIAGNOSIS AND MANAGEMENT OF ACUTE CHOLECYSTITIS

To The Editor:

The observation and review by Dr. Whalen (*Whalen JP: A false-positive hepatobiliary scan: Case report and literature review. J Fam Pract 1987; 24:261-264*) is a useful addition to the family practice literature. However, it raises the issue of the assumption that the first episode of acute cholecystitis is necessarily a surgical disease. The clinical situation presented is one that I have seen occur time and time again in community situations, wherein a relatively young person has been automatically shunted to the surgeons when a clinical diagnosis of cholecystitis has been made regardless of whether the diagnosis is supported entirely by laboratory or scanning, x-ray, or ultrasound evidence.

For years we have supported the position that acute cholecystitis, especially when mild and the first episode, is a medical disease, especially if the evidence for cholecystitis is tenuous.

Over the past 25 years we have treated dozens of patients with mild, suspected first presentations of cho-

lecystitis. Medical therapy has been successful in many of these cases without resorting to surgery. Occasionally we have treated mild recurrences of this condition when they have been separated by many years.

Our experience indicates that internists and, of course, surgeons are much more likely to assume that mild cholecystitis (without evidence of cholelithiasis) is a surgical disease. A "knee-jerk" surgical reaction to this disease is not always necessary.

John C. Brogan, MD
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The preceding letter was referred to Dr. Whalen, who responds as follows:

I agree with Dr. Brogan that a "clinical diagnosis of cholecystitis" is insufficient evidence to justify an operation. The low specificity of symptoms referable to cholecystitis demands some sort of laboratory confirmation before surgery can be recommended.

To respond adequately to Dr. Brogan's comments, however, I would need to know his definition of "cholecystitis." Cholecystitis without evidence of cholelithiasis, so-called "acalculous cholecystitis," is an unusual disease, seen in very special circumstances such as postoperative patients and burn patients. I do not contend that the patient in my case report had cholecystitis. Rather, I am reporting a case where a test that is allegedly highly sensitive and specific for acute cholecystitis was misleading in a patient who demonstrably did not have acute cholecystitis.

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URINARY TRACT INFECTIONS IN ELDERLY WOMEN

To the Editor:

Several aspects of the report by Bertakis and Ross (*Bertakis KD, Ross JL: Office evaluation of urinary tract infections in elderly women. J Fam Pract 1987; 24:72-75*) concerning the evaluation of urinary tract infections in elderly women deserve comment. It would probably be more accurate to use the term *asymptomatic bacteriuria* (ABU) as other authors have,¹ instead of the term *asymptomatic urinary tract infection*, to describe their patients with positive urine cultures. The latter is a subgroup of ABU in which there is some evidence of invasion or inflammation of the urinary tract.

The authors provide a list (Table 2) of the sensitivities and specificities of tests used to detect the presence of ABU. This information is useful but incomplete. It would have been helpful had predictive values also been provided. For example, the Gram stain looks deceptively accurate with a sensitivity of 88 percent and a specificity of 86 percent. However, the positive predictive value (the proportion of patients with an abnormal Gram stain who actually have ABU) in this population is only 50 percent (7 of 14). Positive and negative predictive values could have been calculated easily for each of the tests listed.

A major flaw of this report, rendering the sensitivity, specificity, and prevalence estimates invalid, is the probable misclassification of three of the patients. Most authorities would not consider growth of *Staphylococcus epidermidis*, *diphtheroids*, or mixed flora significant, even at colony counts greater than or equal to 10^5 colonies per milliliter.^{2,3} Were these the patients with normal nitrite and leukocyte esterase tests and white blood cell counts? The authors reportedly recorded epithelial cell counts, a test useful in identifying contamination of urine specimens, but failed to report these data.

Finally, though it is true that the presence of ABU has been associated with increased morbidity and mortality, I know of no study that has demonstrated that treatment of ABU improves these statistics. Therefore, the question of ". . . which tests are most reliable, cost effective and efficient in diagnosing [asymptomatic] urinary tract infections in the elderly population" becomes moot. Attempts to detect ABU in the elderly do not have the characteristics of a good screening program as described by Frame⁴ and is not recommended by that author. Efforts should currently be made to determine whether treatment of ABU reduces morbidity or mortality in the elderly.

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References

1. Platt R: Quantitative definition of bacteriuria. *Am J Med* 1983; 75(suppl 1B):44-52
2. Komaroff AL: Acute dysuria in women. *N Engl J Med* 1984; 310:368-375
3. Roberts JA: Urinary tract infections. *Am J Kidney Dis* 1984; 4:103-117
4. Frame PS: A critical review of adult health maintenance: Part 4. Prevention of metabolic, behavioral, and miscellaneous conditions. *J Fam Pract* 1986; 23:29-39

METHODS FOR COLLECTION OF PAP SMEARS

To the Editor:

Several articles have recently appeared concerning the most effective way of collecting cervical specimens for Papanicolaou testing. Use of a Milex extended-tip spatula and moistened cotton swab have been found to increase the yield of slides with endocervical cells.¹⁻³ It is thought that the presence of endocervical cells is an important indicator of the adequacy for a Papanicolaou smear.⁴ The physicians and nurse practitioners at our clinic have evaluated the effec-

tiveness of the Zelsmyr Cytobrush,* a small brush that collects cells from the endocervical canal.

Four methods of collecting specimens were compared consecutively. A sample size of 85 to 100 was obtained for each method, excluding women who were pregnant or had had a hysterectomy. We found that when a wood Ayre spatula and dry cotton swab were used, 60 percent of slides had endocervical cells; with a plastic Milex spatula and dry swab, 63 percent had endocervical cells; with a Milex spatula and moistened swab, 65 percent had endocervical cells; with a Milex spatula and Zelsmyr Cytobrush, 78 percent of slides had endocervical cells.

The Cytobrush-Milex spatula combination was significantly more effective than the other methods ($P < .05$ by chi-square test) in obtaining endocervical cells. The Cytobrushes are expensive (about 25 cents apiece), but we feel that the increased effectiveness is worth the extra cost. This will be even more important if women and their physicians follow recommendations to have Papanicolaou tests done less frequently.

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* International Cytobrush, Inc, PO Box 7733, Hollywood, FL 33081.

References

1. Hamblin JE, Brock CD, Litchfield L, Dias J: Papanicolaou smear adequacy: Effect of different techniques in specific fertility states. *J Fam Pract* 1985; 20:257-260
2. Brock CD, Ornstein SM, Litchfield L: An improved technique for Papanicolaou smear sampling in postmenopausal women, letter. *J Fam Pract* 1986; 22:498-500
3. Colon VF, Linz LE: The extended tip spatula for cervical cytology. *J Fam Pract* 1981; 13:37-41
4. American College of Obstetricians and Gynecologists: Cervical Cytology, technical bulletin 81. Chicago, American College of Obstetricians and Gynecologists, October 1984