

**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.

*Monistat  
Dual-Pak*

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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.

### BEHAVIORAL SCIENCE CURRICULUM FOR FAMILY PHYSICIANS

To the Editor:

It was interesting and instructive to see how the change of one word in a questionnaire could produce such significant changes as demonstrated in the article on what patients really want by Frowick et al (*Frowick B, Shank JC, Doherty WJ, Powell TA: What do patients really want? Redesigning a behavioral science curriculum for family physicians. J Fam Pract 1986; 23:141-146*). It is indeed tempting to use these results (and others cited) to develop a behavioral science teaching curriculum. As the authors noted, however, we should be reluctant to draw our conclusions regarding emphasis on behavioral science training from these studies. I would further emphasize this point.

Many patients in practice have benefited from active physician intervention in psychosocial issues even when the patients were initially not interested or aware of these issues bothering them. Oftentimes, they were lost in symptoms that were bothering them and were unable or reluctant to open up any personal issues. Many times it took several supportive interventions over time—months to a year—for the patients to gain enough knowledge, insight, and comfort to deal effectively with their psychosocial issues.

If we believed these patients' particular psychosocial issues were of low desirability for physician involvement, the patients would not have

had the opportunity to gain the knowledge and insight to manage their psychosocial problems. I believe we owe it to our patients to become and stay expert enough in psychosocial issues to offer help through active intervention, especially when patients are unaware or reluctant to deal with them.

One way to further determine what patients really want might be to follow patients before and after treatment of psychosocial issues to determine how their perception of what their physician should do has changed.

Robert F. Shadel, MD  
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### ERRATUM

In the May issue of The Journal (*Ganiats TG, Norcross WA, Schneiderman LJ, et al: Intrauterine transfusion: Ethical issues involving a Jehovah's Witness mother. J Fam Pract 1987; 24: 467-472*), on page 472, column 1, in the seventh and eighth lines from the bottom of the column, "The State of California claimed. . ." should read, The State claimed. . .