

### 1983 Budget Shows Continued Cuts

Health programs have taken it on the chin again in the Reagan Administration's new budget proposals for fiscal 1983, the government accounting year that begins October 1.

Despite earlier indications that it would not seek an expansion of health block grants in fiscal 1983, the Administration switched signals and proposed an expansion of block grants to include family planning, black lung clinics and migrant health center programs in the primary block grant.

The fiscal 1983 budget for the Department of Health and Human Services shows heavy cuts in health programs. Most are directed at the Congressional appropriations process, but several would require new authorizing legislation that Congress may be reluctant to approve.

The health block grant would be funded at about \$415 million. The women, infants and children nutrition program would be folded into the maternal and child block grant with a \$300 million cut. This block grant funding would be set at \$1 billion. No changes from the fiscal 1982 funding level will be made in the prevention of alcohol, drug abuse and mental health block grants. The Food and Drug Administration would receive a budget to \$356 million in fiscal 1983 as

compared to its 1982 budget of \$328 million.

The National Health Service Corps field program would receive slightly more than \$100 million, but no new scholarships would be approved. In 1982, Congress provided for 55 new scholarships. The Administration proposed the elimination of the \$9,000 bonus now paid to scholarship recipient physicians.

Nursing scholarships would be funded at about \$17 million, while the nursing assistance programs would get \$42 million.

The Administration is proposing that an \$80 million cap be placed on the amount it will commit to the Health Professions Graduate Student Loan Insurance Fund. Funding for public health education would be at \$5 million, primary care at \$51 million and disadvantaged assistance at \$17 million.

The Centers for Disease Control would receive \$217 million in fiscal 1983, a slight increase over 1982. Within CDC, the Administration wants funding for venereal disease control at \$45 million and childhood immunization at \$29 million.

The National Institutes of Health would receive a small increase in its budget. Cancer would get \$956 million; heart, lung and blood, \$577 million; dental research, \$75 million; arthritis, diabetes, digestive and kidney disease, \$380 million; neurological and com-

municative disorders and stroke, \$275 million; allergy and infectious disease, \$246 million; child health and human development, \$235 million; eye, \$132 million; environmental health sciences, \$160 million; aging \$85 million.

### New Medicare and Medicaid Reductions Proposed

The White House has proposed a \$5 billion package of Medicare and Medicaid reductions for fiscal 1983.

Under the plan, hospital reimbursement would be retroactively reduced by 2%. Other parts of the package are elimination of a subsidy for private hospital rooms; limitation of reimbursement to physicians rendering services in hospital outpatient departments; repeal of mandatory state facility review and indexing the Medicare Part B physician insurance program deductible to the Consumer Price Index.

The package changes the method of paying hospital-based physicians such as radiologists and pathologists to 80% of usual and customary rates. Medicare beneficiaries' coverage would be changed to begin with the first full month of eligibility. Medicare hospital insurance taxes would be levied on the Federal work force to increase Medicare's revenues.

# Now, there's a better Foley catheter.



An important first:

# NIZORAL<sup>®</sup> TABLETS

(ketoconazole)

Safe and effective and offers a number of distinct advantages over nystatin in treating severe oral thrush

## Saves time and trouble for patients and staff

- Simple one-tablet-a-day regimen fosters compliance, facilitates ambulatory and outpatient therapy
- No need for patients to suck on suppositories or swish around nystatin preparations several times a day
- Cost of therapy significantly less than nystatin treatment

## Systemic action can reach remote Candida lesions

- In contrast to the topical action of nystatin, NIZORAL<sup>®</sup> (ketoconazole) can reach asymptomatic lesions in the esophagus or GI tract
- Excellent overall effectiveness...one week clinical cures seen in over 50 percent of patients
- SAFE: Can be administered for prolonged periods; well tolerated. Since possible idiosyncratic hepatocellular dysfunction has been reported, it is desirable to perform appropriate liver function tests before and during treatment, particularly in patients on long-term therapy.

Please see revised brief summary of Prescribing Information on next page.

Jones, Mary 126-34-4439

Date Doctor's orders

9/12/81  
1. Ambulatory as desired  
2. Regular diet  
3. Nizoral 200mg p.o., q.d.



Top: Severe oral thrush before therapy.

Bottom: After 7 days, 200 mg per day oral NIZORAL.

world leader in antimycotic research



**JANSSEN**  
**PHARMACEUTICA**

Janssen Pharmaceutica Inc., 501 George St., New Brunswick, N.J. 08903

# NIZORAL<sup>®</sup> TABLETS

(ketoconazole)

Before prescribing, please consult complete prescribing information, of which the following is a brief summary.

## INDICATIONS AND USAGE

NIZORAL<sup>®</sup> is indicated for the treatment of the following systemic fungal infections: candidiasis, chronic mucocutaneous candidiasis, oral thrush, candiduria, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis. NIZORAL<sup>®</sup> should not be used for fungal meningitis because it penetrates poorly into the cerebral-spinal fluid.

For the initial diagnosis, the infective organism should be identified; however, therapy may be initiated prior to obtaining laboratory results.

## CONTRAINDICATIONS

NIZORAL<sup>®</sup> is contraindicated in patients who have shown hypersensitivity to the drug.

## WARNINGS

Several cases of possible idiosyncratic hepatocellular dysfunction have been reported during NIZORAL<sup>®</sup> treatment. It is important to recognize that liver disorders may occur with NIZORAL<sup>®</sup> therapy. The rare occurrences of liver disorders could be potentially fatal unless properly recognized and managed.

It is desirable to perform liver function tests, such as SGGT, alkaline-phosphatase, SGPT, SGOT and bilirubin, before treatment and at periodic intervals during treatment (monthly or more frequent), particularly in patients who will be on prolonged therapy or who have a history of liver disease. Instances of minor elevations of liver enzyme levels in patients on NIZORAL<sup>®</sup> have been shown to normalize during therapy and may not necessitate discontinuation of treatment. However, if liver function tests are significantly elevated or other signs and symptoms are suggestive of hepatocellular dysfunction, ketoconazole should be discontinued.

In female rats treated three to six months with ketoconazole at dose levels of 80 mg/kg and higher, increased fragility of long bones, in some cases leading to fracture, was seen. The maximum "no-effect" dose level in these studies was 20 mg/kg (2.5 times the maximum recommended human dose). The mechanism responsible for this phenomenon is obscure. Limited studies in dogs failed to demonstrate such an effect on the metacarpals and ribs.

## PRECAUTIONS

**General:** In four subjects with drug-induced achlorhydria, a marked reduction in NIZORAL<sup>®</sup> absorption was observed. NIZORAL<sup>®</sup> requires acidity for dissolution. If concomitant antacids, anticholinergics, and H<sub>2</sub>-blockers are needed, they should be given at least two hours after NIZORAL<sup>®</sup> administration. In cases of achlorhydria, the patients should be instructed to dissolve each tablet in 4 ml aqueous solution of 0.2 N HCl. For ingesting the resulting mixture, they should use a glass or plastic straw so as to avoid contact with the teeth. This administration should be followed with a cup of tap water.

**Information for Patient:** Patient should be instructed to report any signs and symptoms which may suggest liver dysfunction so that appropriate biochemical testing can be done. Such signs and symptoms may include unusual fatigue, nausea or vomiting, jaundice, dark urine or pale stools (see WARNINGS).

**Drug Interactions:** There is no evidence for clinically significant interaction with oral anticoagulant or oral hypoglycemic agents.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** The dominant lethal mutation test in male and female mice revealed that single oral doses of NIZORAL<sup>®</sup> as high as 80 mg/kg produced no mutation in any stage of germ cell development. The Ames' *Salmonella* microsomal activator assay was also negative.

**Pregnancy:** Teratogenic effects: *Pregnancy Category C.* NIZORAL<sup>®</sup> has been shown to be teratogenic (syndactylia and oligodactylia) in the rat when given in the diet at 80 mg/kg/day, (10 times the maximum recommended human dose). However, these effects may be related to maternal toxicity, evidence of which also was seen at this and higher dose levels.

There are no adequate and well controlled studies in pregnant women. NIZORAL<sup>®</sup> should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nonteratogenic effects:** NIZORAL<sup>®</sup> has also been found to be embryotoxic in the rat when given in the diet at doses higher than 80 mg/kg during the first trimester of gestation.

In addition, dystocia (difficult labor) was noted in rats administered NIZORAL<sup>®</sup> during the third trimester of gestation. This occurred when NIZORAL<sup>®</sup> was administered at doses higher than 10 mg/kg (higher than 1.25 times the maximum human dose).

It is likely that both the malformations and the embryotoxicity resulting from the administration of NIZORAL<sup>®</sup> during gestation are a reflection of the particular sensitivity of the female rat to this drug. For example, the oral LD<sub>50</sub> of NIZORAL<sup>®</sup> given by gavage to the female rat is 166 mg/kg, whereas in the male rat the oral LD<sub>50</sub> is 287 mg/kg.

**Nursing Mothers:** Since NIZORAL<sup>®</sup> is probably excreted in the milk, mothers who are under NIZORAL<sup>®</sup> treatment should not breast-feed the child.

**Pediatric Use:** Safety in children under two years of age has been documented in a limited number of cases.

## ADVERSE REACTIONS

NIZORAL<sup>®</sup> is usually well tolerated. Most adverse reactions reported have been mild and transient and have only rarely required withdrawal of therapy.

The most frequent adverse reactions were nausea and/or vomiting, which occurred in approximately 3% of patients. Abdominal pain was reported in approximately 1.2% of patients; pruritus in approximately 1.5% of patients. The following have been reported in less than 1% of patients: headache, dizziness, somnolence, fever and chills, photophobia, diarrhea, jaundice and gynecomastia.

Transient increases in serum liver enzymes have been observed. In the majority of cases, these increases have normalized during therapy or shortly after drug has been discontinued. However, several cases of idiosyncratic hepatocellular dysfunction have been reported (see WARNINGS).

## OVERDOSAGE

In the event of accidental overdosage, supportive measures, including gastric lavage with sodium bicarbonate, should be employed.

## DOSAGE AND ADMINISTRATION

**Adults:** The recommended starting dose of NIZORAL<sup>®</sup> is a single daily administration of 200 mg (one tablet). In very serious infections or if clinical responsiveness is insufficient within the expected time, the dose of NIZORAL<sup>®</sup> may be increased to 400 mg (two tablets) once daily.

## Children:

Children weighing 20 kg or less: . . . . . 50 mg (¼ tablet) once daily  
Children weighing 20-40 kg: . . . . . 100 mg (½ tablet) once daily  
Children weighing over 40 kg: . . . . . 200 mg (1 tablet) once daily

Generally, treatment should be continued until all clinical and laboratory tests indicate that active fungal infection has subsided. Inadequate periods of treatment may yield poor response and lead to early recurrence of clinical symptoms. Minimum treatment for candidiasis is one or two weeks. Patients with chronic mucocutaneous candidiasis usually require maintenance therapy. Minimum treatment for the other indicated systemic mycoses is six months.

## HOW SUPPLIED

NIZORAL<sup>®</sup> is available as white, scored tablets containing 200 mg of ketoconazole debossed "JANSSEN" and on the reverse side debossed "K" and "200." They are supplied in bottles of 60 tablets and in blister packs of 10 x 10 tablets. Rev. Feb. 1982

U.S. Patent Pending  
NDC 50458-220-01 (10 x 10 tablets-blisters)  
NDC 50458-220-06 (60 tablets)

Manufactured by:  
Janssen Pharmaceutica n.v.  
B-2340 Beerse, Belgium

For:  
Janssen Pharmaceutica Inc.  
New Brunswick, New Jersey 08903 USA

world leader in antimycotic research



**JANSSEN**  
PHARMACEUTICA

501 George St., New Brunswick, N.J. 08903

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control topics are now available to augment your training program. *Clinical Bacteriology: Collecting Specimens and Processing them in the Laboratory and Viral Hepatitis: Dangers of Infection and Prevention*, each 15 minutes long, can be obtained as 16mm, or Super 8mm film; U-matic, VHS, VCR, or Betamax video tapes.

There is still some uncertainty about the relationship between correct sampling methods in the ward and the accurate biological diagnosis in the clinical laboratory, the latter of which can only be guaranteed by the former. *Clinical Bacteriology* shows modern methods of identifying bacteria and preparing an antibiogram, as well as demonstrating in clinic or surgery the correct ways of sampling sputum, tracheal secretions, midstream urine and blood.

*Viral Hepatitis* discusses the different modes of transmission and—considering the latest scientific research—gives advice on nursing patients and self-protection in clinics, general wards, dialysis units, and in dental practice. Several forms of viral hepatitis occur.

## Infection Control Nurse

Sarasota, Florida

Florida's premiere medical facility now has a challenging opportunity for a Registered Nurse who has received training at the Center of Disease Control and who possesses at least 2 years experience in infectious control at our 656-bed facility located on the Gulf of Mexico in Sarasota. Florida state licensure eligibility is also required.

At SARASOTA MEMORIAL, professional and personal lifestyles excel to new heights. Our friendly, personalized approach to health care provides an outstanding working environment, while the miles of white sand beaches along the Gulf make recreational possibilities almost limitless.

If you're ready for a step up in your career, make your move to SARASOTA MEMORIAL. For more information, please contact:



Joan Bush, RN, Nurse Recruiter  
**Sarasota Memorial Hospital**  
1901 Arlington St., Dept. IC  
Sarasota, Florida 33579  
(813) 953-1401 Collect Please  
an equal opportunity employer m/f

# And we can prove it.

The research findings clearly show that our Silicone Elastomer Coated Foley Catheter is better than Teflon® and other silicone coated catheters.

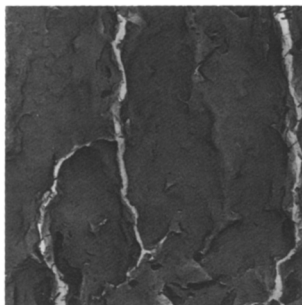
And is also better than the more costly all-silicone Foley catheter.

The reason: at American Pharmaseal, we start with a high-quality silicone on high-quality latex. Then, we use a specially developed coating process that provides an extremely smooth coating which minimizes sediment and encrustation build-up.

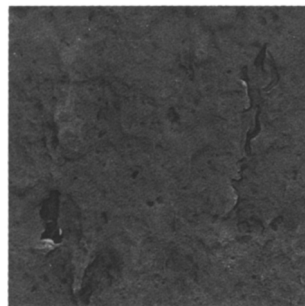
Plus, an inert formulation that protects against irritation. And our silicone elastomer coating is non-tacky and doesn't attract lint.

The result: a smoother surface, easier insertion and less encrustation build-up... for more patient comfort. See for yourself:

**Foley catheter surface structure comparisons using a scanning electron microscope (1000X):<sup>1</sup>**

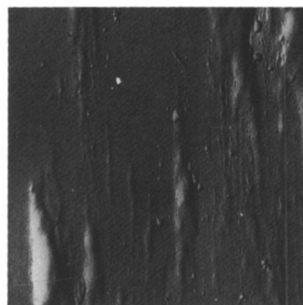


**A Teflon Coated Latex Catheter.** Note surface cracks and jagged looking coating.

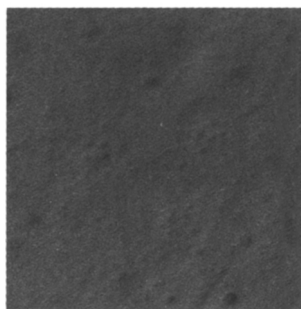


**B Competitive Silicone Coated Catheter.** Smoother than Teflon coated, but surface cracks and uneven deposit formations are still evident.

<sup>1</sup>For further details on study, contact American Pharmaseal.



**C All-silicone Foley Catheter.** A relatively smooth surface, although there are some bumps and decompressions due to catheter extrusion process. The debris can probably be attributed to its tacky surface.



**D American Pharmaseal Silicone Elastomer Coated Foley Catheter.** Without question, the smoothest catheter surface in this study.

**In addition to the coating, we added all these important design features.**

**Strong, flexible catheter shaft** allows easier insertion for extra patient comfort.

**The thicker funnel** resists collapsing and "kinking-off" during irrigation procedures, yet provides a snug fit between the Foley catheter funnel and drainage bag connector.

**Larger eyelets** reduce chances of clogging, but without compromising tip strength.

**Reinforced tip** offers dependable strength and protection against puncture if a stylet is used.

The American Pharmaseal Silicone Elastomer Coated Foley Catheter. A better Foley catheter. But don't take our word for it. Review the research findings now available.

Just ask your American Pharmaseal representative for more information, **including an illustrated brochure that shows the reduced amount of encrustation build-up with our catheters in a comparison study conducted on rabbits.** Or write us directly at American Pharmaseal, P.O. Box 1300, Glendale, CA 91209.



**American Pharmaseal**