16th Annual Meeting of the International Society of Blood Purification

The 16th Annual Meeting of the International Society of Blood Purification (ISBP) will be held October 4–6, 1998, in Newport, Rhode Island. Sir Roy Calne will deliver the annual award lecture. Planned symposia include: new directions in pre-ESRD therapies; current thinking about diabetes in renal failure; and the influence of a changing health care infrastructure on the management of kidney failure patients. There will also be free communications and poster presentations. For more information, visit our website at http://www.ISBP.org or contact Michael J. Lysaght, P.O. Box 2480, Providence, RI 02906; Telephone: (401) 863-7512; fax: (401) 863-1753; e-mail: ISBP98@Brown.edu.

26th Annual Seminar in Pediatric Nephrology: Millennium Mandate

The 26th Annual Seminar in Pediatric Nephrology: Millennium Mandate will be held February 26 through March 2, 1999, at the Fontainebleau Hilton Resort and Spa in Miami Beach, Florida. The meeting is sponsored by the Department of Pediatrics, University of Miami School of Medicine. For more information, contact Dr. Jose Strauss, Division of Pediatric Nephrology, University of Miami School of Medicine, P.O. Box 016960, Miami, FL 33101. Telephone: (305) 585-6726; fax: (305) 547-1709; e-mail: jstrauss@peds.med.miami.edu. Or visit the website at http://pediatrics.med.miami.edu/nephrology.htm.

13th Comprehensive Nephrology Review Course

The 13th Comprehensive Nephrology Review Course will be held October 2 to 8, 1998 at the Beverly Hilton Hotel, Beverly Hills, CA. The deadline for reservations is September 1. The course is sponsored by the office of Continuing Medical Education, UCLA School of Medicine. Participants can earn up to 44.5 hours of Category I credit toward the AMA Physicians Recognition Award. Enrollment fees are $800 for physicians and $700 for residents. To enroll, call (310) 794-2620 or fax (310) 794-2624, or write the Office of Continuing Medical Education, Comprehensive Nephrology Review Course, Office of CME, 10920 Wilshire Boulevard, Suite 1060, Los Angeles, CA 90024-6512.

Psychonephrology 1998, Eleventh International Conference on Psychonephrology

Psychonephrology 1998, the eleventh international conference on psychonephrology, will be held in New York City October 9–11, 1998. This meeting will cover the psychosocial and ethical issues confronting patients with renal failure and offer information for the professional people caring for these individuals. Internationally recognized experts in this area will present in plenary sessions, concurrent large sessions, small group discussions, and a debate. The keynote speaker will be Dr. Eli A. Friedman. Sixteen and a half hours of AMA Category I CMA credit are offered. Continuing education credits will also be available for social workers and nurses. Tuition is $200. For more information, including submission of abstracts for Free Communication, contact Dr. Norman B. Levy, Coney Island Hospital, 2601 Ocean Parkway, Brooklyn, NY 11235. Fax: (718) 616-5314.

2nd Finlayson Colloquium on Urolithiasis: Calcium Oxalate Nephrolithiasis

The second Finlayson Colloquium on Urolithiasis will be held January 29 to 31, 1999, at the University of Florida, Gainesville, FL. The program will consist of symposia followed by roundtable discussions and will include the following topics: Sites and Mechanisms of Crystal and Stone Formations; Crystal/Tissue Interactions; Modulators of Crystalization; Oxalate and Its Transport; Lithotripsy and Other Therapies. Presentations are by invitation only. For more information, contact Dr. Saeed R. Khan, Department of Pathology, Box 100275, College of Medicine, University of Florida, Gainesville, FL 32610-0275. Telephone: (352) 392-3473; fax: (352) 846-0155; e-mail: mirza.pathology@mail.health.ufl.edu.

XVth International Congress of Nephrology and XIXth Latin American Congress of Nephrology

The International Society of Nephrology and Latin American Society of Nephrology and Hypertension are planning the XVth International Congress of Nephrology and XIXth Latin American Congress of Nephrology, May 2 to 6, 1999, in Buenos Aires, Argentina. A continuous medical education (CME) course will be offered in English and Spanish. Some of the themes include: Molecular Biology for the Clinician; Metabolic Bone Disease; Management of Urinary Tract Infections; Water, Acid-Base, and Electrolyte Disorders; Management of Hypertension in Renal Patients; Vascular Access Complications; CAPD; Quality and Outcome of Dialysis; and Essential Hypertension. Topics for the main scientific program include: Hormones and the Kidney; Nonimmune Injury of the Kidney; and Renal Transplantation. Deadline for Abstracts is September 22, 1998. For young physicians and scientists who are submitting abstracts from developing countries, 120 ISN travel grants of $1000 (US) will be available. For more information, contact the Secretariat of the XV ICN, Ayacucho 937, 1° “G”, 1111 Buenos Aires, Argentina. Telephone: (+54 1) 812-1021; e-mail: bayfem@ibm.net.
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NEORAL® Oral Solution (cyclosporine oral solution for microemulsion)

CAUTION: Federal law prohibits dispensing without prescription.

The following is a brief summary for transport only; see full prescribing information for complete product information on the other indications for immunosuppressants and vaccines, as well as Contraindications, Warnings and Adverse Reactions. Patients should be informed of the importance of repeated laboratory tests while they are receiving NEORAL®.

Patients should be advised to take NEORAL® immediately before or twice a day and to maintain the same daily dose throughout the treatment period. Patients should not be exposed to temperatures that exceed 40°C (104°F) during storage and transport. See Instructions for Use enclosed with the product. The bottle and ampoule should be avoided.

Contraindications: NEORAL® is contraindicated in patients with a hypersensitivity to cyclosporine or any of the ingredients of the formulation.

Warnings: (See Section Warnings) Cyclosporine, the active ingredient of NEORAL® may cause nephrotoxicity and neurotoxicity. An increased incidence of episodes of cyclosporine toxicity including renal damage and/or neurotoxicity is a potential consequence of NEORAL® and traditional renal function tests may be normal during therapy. Therefore, patients receiving NEORAL® require frequent monitoring of renal function, and electrophysiological testing. Laboratory tests should be used to monitor renal function and in patients not properly adjusted, cyclosporine therapy can be associated with the occurrence of structural kidney damage and permanent renal function loss. Patients receiving NEORAL® require frequent monitoring of renal function, and electrophysiological testing. Laboratory tests should be used to monitor renal function and in patients not properly adjusted, cyclosporine therapy can be associated with the occurrence of structural kidney damage and permanent renal function loss.

Adverse Reactions:

Renal:

An increased in serum creatinine and BUN may occur during NEORAL® therapy and reflect a reduction in the glomerular filtration rate, the decrease in drug clearance and, therefore, an increase in cyclosporine plasma concentrations. This elevation is likely to become more pronounced without dose reduction or discontinuation.

Bones and Joints:

If NEORAL® is used in association with steroids, a 1:1 ratio of corticosteroid to cyclosporine (based on dose) may be necessary in order to prevent bone loss.

It is not unusual for serum creatinine and BUN levels to be elevated during cyclosporine therapy. These elevations in renal function may not necessarily indicate rejection, and each patient must be fully evaluated before dosage adjustment is instituted.

Based on the historical Sandimmun® experience with oral solution, nephrotoxicity associated with cyclosporine has been noted in 25% of cases of renal transplantation, 39% of cases of cardiac transplantation, and 37% of cases of liver transplantation. Mild nephrotoxicity was generally noted 3-2 months after renal transplant and consisted of an increase in the amount of proteinuria, BUN, and creatinine between 1-5 mg/dL.

These elevations were often responsive to cyclosporine dose reduction.

More severe renal dysfunction was reported in 3-4% of patients treated with a rapidly rising dose of BUN and creatinine. Since these events are similar to renal rejection episodes, care must be taken to differentiate between these two forms of nephrotoxicity. Although specific diagnostic criteria which reliably differentiate renal graft rejection from drug toxicity have not been found, a small number of parameters have been associated with rejection or the other. It should be noted however, that no single parameter (eg, plasma creatinine) was associated with a particular clinical event.

A form of a cyclosporine-associated nephrotoxicity is characterized by arterial renal parenchymal destruction and microangiopathic hemolytic anemia which may result in graft failure. The vasculitis can occur in the absence of injection and is accompanied by eosinophilic interstitial nephritis. Patients with cyclosporine-induced graft failure have been noted to have increased serum creatinine despite a decrease or discontinuation of cyclosporine renal therapy. Renal biopsies from these patients will show evidence of tubular necrosis, arteriolar fibrinoid necrosis, and eosinophilic crescents. Arteriolar fibrinoid necrosis is a pathognomonic finding associated with this form of renal toxicity.

In the occurrence of interstitial nephritis, the renal failure may be reversible if cyclosporine is promptly discontinued. Where there is evidence of interstitial nephritis, cyclosporine should be discontinued promptly. If renal failure is refractory to discontinuation, measures to improve renal perfusion, acidosis, and anemia should be employed. The changes in renal function tests may be reversible if treatment is started within 48 hours of the appearance of the renal failure. The mortality rate from this form of renal toxicity is high.

Another form of cyclosporine-associated nephrotoxicity is characterized by the formation of cyclosporine-containing casts in the renal tubules. This form of renal toxicity is reported to occur with doses of cyclosporine greater than 10 mg/kg/day and may present with a sudden fall in renal function. The treatment of the renal failure includes restoration of adequate renal perfusion, improvement of acidosis, and treatment of the complications of renal failure.

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What Happens When Critical Information Is Left Open to Interpretation?

When it comes to cyclosporine therapy, the question of which formulation a transplant recipient receives can make a critical difference. Currently, there are two cyclosporine formulations widely available—Neoral® (cyclosporine for microemulsion) and Sandimmune® (cyclosporine, USP), both of which have been proven through extensive clinical experience to prevent organ rejection. Because of differences in formulation, Neoral and Sandimmune® are not bioequivalent and cannot be used interchangeably without careful monitoring of cyclosporine blood levels and dosage adjustments based on individual response to ensure optimal therapy (safety and efficacy).

Unfortunately, despite the serious clinical consequences of a transplant recipient inadvertently receiving the wrong formulation, many prescriptions are still being written without brand specification.

The Potential for Prescription Error Is High…

A survey of 2830 prescriptions for cyclosporine products (Neoral or Sandimmune) revealed that approximately 24% of all prescriptions do not specify intended brand by name. Furthermore, when a follow-up study investigated how pharmacists chose which formulation to dispense, only 22% of the pharmacists interviewed said they would call the physician to clarify a “cyclosporine” prescription—thus leaving critical information open to interpretation.

…and Cause for Serious Concern

With similar numbers of prescriptions written for Neoral and Sandimmune (36% and 40%, respectively), the intent of physicians writing “cyclosporine” is becoming less clear. Without a pharmacist calling to verify the intended brand of cyclosporine, transplant recipients could receive the wrong formulation of cyclosporine. As a result, these patients could be in danger of falling outside of their narrow therapeutic range and at greater risk for organ rejection, potential graft loss, and increased toxicities.

You Can Ensure the Right Formulation for Your Patients

The good news is the survey also found that when a prescription specified either “Neoral” or “Sandimmune,” the intended brand was dispensed. Therefore, to protect patients from the dangers of receiving an unintended formulation, the physician should specify “Neoral” or “Sandimmune” by brand name, and the pharmacist should call the physician to verify intended brand of any prescription written for “cyclosporine.”

Doing so will make the critical difference for each transplant recipient and help maximize the benefits of his or her individualized immunosuppressive therapy.