

The Diagnosis: how doctors find the source of your symptoms.

Meet the physicians of Premier's new Internal Medicine Division.

When is participating in a Research Trial right for you?

# PremierHealth

The experience you need... the compassion you deserve

FALL 2013

## Introducing Premier Women's Center for Continence and Sexual Health



The magazine of PREMIER *medical group of the Hudson Valley*

### Gastroenterology Division

With offices in...

Poughkeepsie: 845-471-9410  
 New Windsor: 845-562-0740  
 Fishkill: 845-897-9797  
 Kingston: 845-471-9410

Sunil K. Khurana, MD, FAGG  
 Khurram I. Ashraf, DO  
 Salvatore M. Buffa, MD  
 Robert S. Dean, MD  
 Farshad Elmi, MD  
 Arif M. Muslim, MD  
 Zana Nikolla, MD  
 Peter M. Varunok, MD, FAGG

### Allied Professionals

Kimberly Nieves, NP  
 Thanh-Ho Nguyen, PA

### Internal Medicine Division

With offices in...

Poughkeepsie: 845-483-5858  
 Newburgh: 845-561-3348  
 Fishkill: 845-838-8480

Davide DeBellis, M.D.  
 Alan H. Gross, M.D., FCCP  
 Carol E. Miyake, M.D.  
 Lorraine Nardi, M.D.  
 William G. Rohan, M.D.  
 Henry H. Westmoreland, M.D., FACP

### Allied Professionals

Mele Catell, RPA  
 Mark Farrell, RPA-C  
 J. David Haldeman, RPA-C  
 Kirsten Laux, FNP  
 Scott Markumas, RPA-C  
 Cathy Relyea, ANP, CDE

### Urology Division

With offices in Poughkeepsie, Kingston,  
 Fishkill, Newburgh and Rhinebeck  
 MAIN PHONE: 845-437-5000

Evan R. Goldfischer, MD, MBA, FACS  
 Scott Kahn, MD, FACS  
 Daniel Katz, MD  
 Jason Krumholtz, MD  
 Mark R. Libin, MD  
 Walter Parker, MD  
 Paul K. Pietrow, MD, FACS  
 Paul Pomerantz, MD, FACS  
 Naeem Rahman, MD  
 Jaspreet Singh, DO  
 Michael Solliday, MD  
 Conrado N. Tojino, Jr., DO, FACOS  
 Praneeth Vemulapalli, MD  
 Michael Young, MD, FACS

### Allied Professionals

David M. Boss, RPA-C  
 Samantha S. Tojino, FNP-C  
 Kevin Torrens, RPA-C  
 Frances Traver, ANP-C  
 Marylu Williams, FNP

**The physicians of Premier Medical Group are affiliated with:**  
 Northern Dutchess Hospital  
 St. Francis Hospital  
 St. Luke's Cornwall Hospital  
 Vassar Brothers Medical Center

Contents of this magazine © 2013, Premier Medical Group of the Hudson Valley. Reproduction in whole or in part is strictly prohibited without the prior express written permission of Premier Medical Group.

This publication does not, in any way, substitute for professional medical care and the articles herein should not be considered medical advice in any manner. Consult your physician before undertaking any form of medical treatment or adopting any dietary program.



PremierHealth is published for Premier Medical Group of the Hudson Valley by Martinelli Custom Publishing

- Creative Director: Alex Silberman
- Publisher: Thomas Martinelli

Premier Medical Group Editor: Isabel Dichiarà  
 [idichiarà@premiermedicalhv.com]

## IN THIS ISSUE

### 3 Introducing Dr. Zana Nikolla

The GI Division's newest physician extends and completes our range of subspecialties.

### 4 New approaches to treating celiac disease



Researchers are working on a variety of treatments that may soon make a big difference in the lives of those with celiac disease.

### 5 What you need to know about bladder cancer

More than 70,000 Americans are diagnosed with this cancer every year. How can you avoid being numbered among them?

### 6 Internal Medicine comes to Premier

The expertise, experience and variety of subspecialties makes this group of internists a perfect fit for Premier.



### 8 GI Diagnosis: Beyond the symptoms

A trip to Mexico does not explain this case of diarrhea.

### 9 Is a research trial right for you?

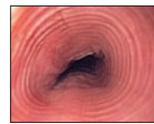
A careful consideration of the potential risks and benefits is necessary before you make your decision.

### 10 Premier Women's Center for Continence and Sexual Health

An important new resource for the women of the Hudson Valley opens its doors.

### 13 Urology Diagnosis: Not always what it seems

A woman's voiding symptoms do not lead to the usual suspects.



### 14 What you need to know about Eosophilic Esophagitis

Allergies and the immune system are at the root of this newly recognized disease.

### 17 Erectile dysfunction: when medications fail

PDE5 inhibitors, such as Viagra and Cialis, have revolutionized treatment of ED, but they do not work for every man.

### 18 Leaders in their fields

The physicians of Premier play an outsized leadership role at our area's hospitals.

### 20 Faces of Premier: Dr. Paul Modica, anesthesiologist

[premier news]

# Introducing Dr. Zana Nikolla, the GI Division's newest physician

We now provide every possible GI service, comparable to what you can find in a full-fledged academic medical center.

Premier Medical Group is pleased to welcome Zana Nikolla, M.D., who joined the Gastroenterology Division in August, following her fellowship in gastroenterology at Bridgeport Hospital, Yale New Haven School of Medicine. While at Yale, Dr. Nikolla also completed a special sub-fellowship in gastrointestinal (GI) motility from the American Neurogastroenterology and Motility Society at Temple University in Philadelphia.

GI motility refers to the movement of food from the mouth through the pharynx (throat), esophagus, stomach, small and large intestines, and out of the body. Problems related to motility include gastroesophageal reflux disease (GERD), difficulty swallowing and non-cardiac chest pain, esophageal spasms and achalasia, gastroparesis (delayed stomach emptying), and severe constipation.

"It was Dr. Nikolla's special training and expertise in GI motility—an area we were not yet fully covering—that made her so attractive to us, along with her great personality and the fact that she shares the value system of our group," says Dr. Sunil Khurana, director of the GI Division. "We now provide every possible GI service, comparable to what you can find in a full-fledged academic medical center."

Dr. Nikolla's journey to Premier began in her native Albania. While in medical school there, Nikolla says, she "fell in love with gastroenterology. It made sense to me." She saw it as an area in which patients were underserved. "Often patients and physicians are not aware that there are diagnoses and treatments that can address many of the gastrointestinal issues that afflict people."

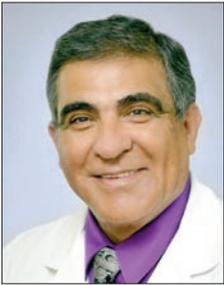
Eleven years ago, after earning her medical degree and practicing for several years in her native country, Dr. Nikolla came to the United States with her husband. Upon passing all the necessary board exams, she completed her residency at Jacobi Medical Center in the Bronx, where she served as chief resident. "It was an amazing learning experience," Nikolla recalls. "I was able to see patients from all over the world, including some of my own compatriots."

Dr. Nikolla is fluent in English, Spanish and Italian. Her gift for languages may stem from the fact that her mother was a physician and her father was a journalist who often wrote about health care topics. "Medical talk was very common in our house and I found that Latin came very easily to me," she says, "and that helped me learn other languages."

Now settled into her new home in the Hudson Valley, Dr. Nikolla is looking forward to the changing colors of fall. "This is such a beautiful place," she says. "I am really excited about being here. I am excited to be part of Premier Medical Group. The physicians are very well respected in the community and dedicated to their patients' care. I identify with that because the overall well-being of my patients is the focus of my practice. My patients mean everything to me."



# New approaches to treating celiac disease



Sunil K. Khurana, MD, FACC

For the last thirty years, the best we could do for our patients with celiac disease was advise them to go on a gluten-free diet. Not only is complying with this diet difficult, contamination introduces gluten to many supposedly gluten-free foods. Unfortunately, a significant percentage of patients who rigorously follow the diet, will still experience symptoms. Finally, several treatments being developed hold forth the prospect of better management of celiac disease and an enhanced quality of life for those who have it.

vitamin B missing from most gluten-free grains.

“Another promising approach involves developing a therapeutic vaccine for celiac disease,” Khurana says. “It works in the same way as the therapy for desensitizing people with allergies. You start with a low dose and gradually increase it to desensitize people to the effects of the gluten.” The vaccine will be given in multiple small doses, by injection, creating immune tolerance and preventing the damaging inflammation of CD.

## On the near horizon

One of the treatments closest to becoming available, perhaps within the next five years, is a zonulin inhibitor. “Zonulin is a human protein that

Celiac disease (CD) is a chronic inflammatory autoimmune disease of the small intestine. People with CD cannot tolerate gluten, a protein present in wheat, barley and rye. When they do consume gluten, their immune systems respond by damaging or destroying the villi—tiny, fingerlike protrusions lining the small intestine—which normally allow nutrients to be absorbed through the walls of the small intestine into the bloodstream. Without healthy villi, a person becomes malnourished, no matter how much food he or she consumes.

Years of research have yielded insights into the physiological processes contributing to CD, which include genetic vulnerability, the gluten trigger and an unusual permeability of the intestines that allows gluten to penetrate. The new treatments in the pipeline seek to address each of these factors.

“Since gluten is the problem, one strain of research in development is striving to genetically modify gluten and remove its toxicity for people with CD,” says Dr. Sunil Khurana, director of Premier’s GI Division. Studies show that it is possible to breed gluten proteins that do not stimulate an autoimmune response. If this approach is successful, it will be possible to introduce “detoxified” wheat into the CD diet, making it easier to enjoy well-balanced meals containing the

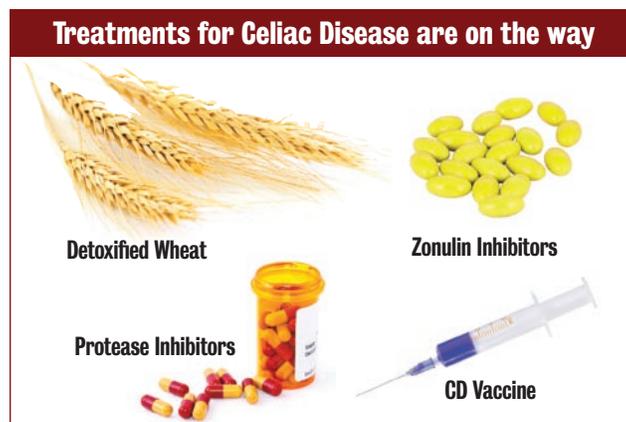
contributes to the intestinal damage caused by celiac disease,” Khurana explains. “Whereas the villi are normally tightly attached, exposure to zonulin (stimulated by a component in gluten) breaks them up, decreases the barrier and increases the permeability of the villi. The zonulin inhibitors will interrupt the process and keep the gluten from getting into the cells and damaging the villi,” Khurana says.

The drug, as used in current studies, is designed to be taken in pill form before a meal that includes food containing gluten. The FDA has recently approved the study of this drug in the treatment of Crohn’s disease, which is also affected by zonulin production.

“A quite new and fascinating area of investigation involves a set of probiotics that contain protease,” says Khurana. “The protease enzymes will deactivate the gluten that is in the stomach, before it can reach the small intestines where it causes the damage of CD.

The probiotics, for their part, will contribute to mucosal healing in the wake of previous CD damage. These protease pills are being tested with people who have been following a gluten-free diet yet are still experiencing symptoms.”

“It is true that none of these treatments are clinically available just yet,” says Khurana. “They mark a set of breakthroughs that offer real hope for people with celiac disease. At Premier Medical Group, we are involved in ongoing research trials.”



WHAT YOU NEED TO KNOW ABOUT

# Bladder Cancer



Praneeth Vemulapalli, MD

Patients who experience urinary pain, frequency or urgency, especially if accompanied by visible signs of blood in the urine (gross hematuria), should consult a physician or urologist. Although these symptoms are commonly associated with a urinary tract infection, they may also be the sign of something more serious, such as precancerous lesions or bladder cancer.

It is estimated that before this year is over, more than 72,000 Americans—most of them over age 55 and two-thirds of them male—will be diagnosed with bladder cancer. When found in its earliest stages—as it is for approximately 75 percent of bladder cancer patients—the cure rate is high. Which makes it all the more important to take heed of possible symptoms and warning signs.

Patients who experience urinary pain, frequency or urgency, especially if they are accompanied by visible signs of blood in the urine (gross hematuria), should consult a physician or urologist. Although these symptoms are commonly associated with a urinary tract infection, they may also be the sign of something more serious, such as precancerous lesions or bladder cancer.

“The most telltale warning sign of bladder cancer is blood in the urine,” says Praneeth Vemulapalli, M.D., of Premier’s Urology Division. “When a patient presents with urinary symptoms, tests will reveal the presence of microscopic hematuria, amounts invisible to the naked eye. If blood is present, the first thing we do is investigate where the bleeding is coming from,” Dr. Vemulapalli says. “We conduct an upper urinary tract imaging study of the kidneys and ureters to rule out such things as kidney stones, infections or other potential sources of upper tract bleeding.”

In order to evaluate the lower urinary tract, cystoscopy is performed, a procedure in which a small camera provides views of the urethra and bladder. Cystoscopy is considered the “gold standard” for evaluating the lower urinary tract. We can also perform narrow band imaging to reveal tumors that might not be

visible under white light cystoscopy.

If a tumor is located, the physician will perform an endoscopic transurethral resection, a procedure in which the tumor is scraped off the bladder lining. The pathology department grades the tumor for its severity and to help determine the appropriate course of follow-up care.

In the least aggressive cases, known as papillary carcinomas, removing the tumor from the bladder lining may be the only treatment required. If the cancer appears more aggressive, but is still limited to the bladder

lining, intravesical chemotherapy can be used to kill remaining cancer cells in a localized manner. This involves inserting a drug directly into the bladder through a catheter, either as a single dose shortly after the bladder resection, or over the course of six weekly treatments. Such targeted treatment spares the patient many of the unpleasant side effects of systemic chemotherapy, such as nausea and hair loss.

More serious cases may require a combination of chemotherapy and immunotherapy. The most aggressive cases of bladder cancer—in which the cancer has spread to the bladder muscle itself—may require either a partial or a radical cystectomy, removing a portion of the bladder or the entire bladder. In the case of a radical cystectomy, there are several options for accommodating bladder function, including creation of a “neo-bladder” that permits close to normal urinary function or an ileal conduit to divert urine outside of the body.

“If found early, the success rate for the treatment of bladder cancer is very high and most patients can go on to live full and complete lives without comprising their quality of life in any way,” says Dr. Vemulapalli. It should be noted that bladder cancer has a high recurrence rate, however with close follow-up, patients have a very good chance of beating and surviving the disease.

For this reason, people who have had bladder cancer are advised to commit to lifelong follow-up exams. The American Academy of Urologists calls for assessment every three months in the first two years after diagnosis, every six months for the next two to three years, then annually thereafter.

**MANY PEOPLE ARE SURPRISED TO LEARN SMOKING IS THE PRIMARY CAUSE OF BLADDER CANCER, RESPONSIBLE FOR ABOUT HALF THE CASES OF THE DISEASE IN BOTH MEN AND WOMEN. SMOKERS ARE AT LEAST THREE TIMES AS LIKELY TO GET BLADDER CANCER AS NONSMOKERS.**

**“The carcinogens in tobacco that are absorbed through the lungs are filtered through the kidneys and ultimately collect in the bladder, where they can stay for long periods of time, until the patient urinates,” Dr. Vemulapalli says. “My advice to patients who want to avoid bladder cancer—and many other health problems—is simple: Stop smoking. Now.”**

[new developments]

# Internal Medicine comes to Premier



This fall, New Century Medical Associates merged with Premier Medical Group of the Hudson Valley. For our patients, the result will be seen in a greater array of medical services and a more seamless health care experience.

Premier Medical Group's merger with New Century Medical Associates brings an Internal Medicine Division marked by experience to the practice. These high-quality physicians have years of experience in the region and in the course of that time have established a great reputation in the community. With existing offices in Fishkill, Newburgh and Poughkeepsie, their geographic presence dovetails with the rest of the practice, making it convenient for all our patients.

Premier is now able to offer another dimension of care to its patients: primary care with a subspecialty focus. The board-certified physicians of the Internal Medicine Division are also credentialed in a range of subspecialties that include, endocrinology, geriatric medicine, hypertension, nephrology and pulmonology. We are pleased and excited to welcome them.

“One important reason that led us to join Premier is its focus on continuity and quality of care. It is a practice philosophy we have in common.

Even though we are now part of a large group, we want to maintain the personal connection we have with our patients. We have a tendency to spend more time with our patients than some practices, and we see our patients when they are in the hospital. Some groups would turn them over to the care of a hospitalist, but we know our patients and follow their progress to maintain continuity of care.

In some larger organizations the patient can become a number, but not at Premier, and that too made us comfortable with the merger. We did not want to become cogs in a large medical machine and we did not want our patients to become cogs. Premier has the right approach.

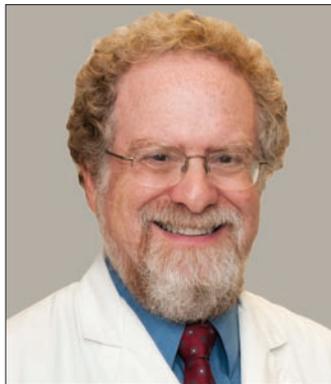
We are looking forward to a greater integration of medical care for our patients as well. In Dr. Nardi's case, as a nephrologist there is a good deal of crossover between the practices. It is not uncommon for her to have a patient who ultimately needs urological intervention, or for the urologists to have a patient needing nephrological help. Of course, now there will be even better information sharing, and communication.

As an endocrinologist, Dr. Miyake has many patients with diabetes who develop problems of the digestive tract and the urinary tract. Her patients' problems mesh well with our new capabilities.

Premier's resources have made it easier for us to convert to the latest technology in electronic medical records to better monitor our patients' data and integrate it into their care. All in all, this is an exciting time.”

—Dr. Alan Gross  
and Dr. Lorraine Nardi

## Physicians of Premier's Internal Medicine Division



**Alan H. Gross, MD**

**SUBSPECIALTY: Pulmonary Medicine**

Dr. Gross is board certified in both Internal Medicine and Pulmonary Medicine. Following a degree in biology at Brandeis University, he attended medical school at New York Medical College continuing with both Internship and Residency at Maimonides Medical Center in Brooklyn, NY. In addition, Dr. Gross completed a Fellowship in pulmonary medicine at Saint Luke's-Roosevelt Medical Center in New York City.



**Lorraine Nardi, MD**

**SUBSPECIALTIES: Nephrology, Hypertension**

Dr. Nardi is board certified in both Internal Medicine and Nephrology. Following a degree in biology at New York University, Dr. Nardi attended medical school at New York Medical College. She continued with both Internship and Residency at Lenox Hill Hospital in New York City. Dr. Nardi completed a Fellowship in nephrology at Mount Sinai Medical Center in New York City.



**David Michael DeBellis, MD**

Dr. DeBellis is board certified in Internal Medicine. Following a degree in natural sciences at The Johns Hopkins University, he attended medical school at New York Medical College. He continued with both Internship and Residency at New York Medical College/Westchester County Medical Center.



**Carol E. Miyake, MD**

**SUBSPECIALTY: Endocrinology**

Dr. Miyake is board certified in both Internal Medicine and Endocrinology. Following a bachelor's degree, cum laude, from Kalamazoo College, Dr. Miyake attended medical school at the University of Michigan in Ann Arbor, doing her Internship and Residency at the Hospital of St. Raphael, a Yale University Affiliate. Dr. Miyake completed a Fellowship in renal and metabolism at the Hospital of St. Raphael and an additional Fellowship in endocrinology at New York Medical College, Valhalla, NY.



**William G. Rohan, MD**

Dr. Rohan is board certified in Internal Medicine. Dr. Rohan attended medical school at the State University of New York at Stony Brook and continued his Residency there. He has special experience in Emergency Medicine.



**Henry H. Westmoreland, MD**

**SPECIAL INTEREST: Geriatric Medicine**

Dr. Westmoreland is board certified in Geriatric Medicine. Following a bachelor's degree in chemistry at Princeton University, he attended medical school at The Johns Hopkins University in Baltimore. He did his Internship and Residency at Lenox Hill Hospital in New York City. Dr. Westmoreland completed a Fellowship in internal medicine at Georgetown University Hospital and studied geriatrics at Mt. Sinai and NYU Schools of Medicine.

# Beyond the symptoms



Zana Nikolla, MD

A 46-year-old woman, referred by her primary care physician, presents with chronic diarrhea. She has suffered with loose stools for nearly two years, beginning on a trip she and friends took to Mexico. Many of her acute symptoms, such as cramping and excessive gas, abated over the course of a few days. Her bowel movements, however, have never returned to normal.

## THE HISTORY

Patient describes her stools as being greasy, grayish in color and malodorous, but reports no blood or mucus in the stool. Her bowel movements sometimes occur upon waking; other times immediately after meals. She feels bloated and fatigued and has lost 10 pounds during the past year. She wonders if work stresses are contributing to her diarrhea.

Patient has Type I Diabetes and her mother suffers from hypothyroidism. She does not use tobacco, alcohol or illicit drugs. Two months ago, she fractured her wrist while playing basketball. X-rays taken at that time revealed osteopenia (decreased bone density), for which her primary care doctor started her on vitamin D and calcium. She had no problem tolerating those supplements.

## THE EXAM

Physical examination reveals the patient to be thin, with normal heart and lung exam. She has tiny aphthous ulcers (canker sores) in her mouth, but reports she has always had them and they do not bother her. Patient has a distended abdomen, but no tenderness to touch. Rectal exam reveals no tenderness or masses and there is no blood in the stool.

## DIAGNOSIS: COMPLICATED, BUT CLEAR

Based on the patient's symptoms alone, the cause of her diarrhea could be infection, lactose intolerance, celiac disease, inflammatory bowel disease, cancers of the gastrointestinal tract or irritable bowel syndrome.

- Stool studies for bacteria and parasites come back negative, ruling out infection. Blood work reveals the patient has iron-deficiency anemia, as well as low vitamin D and low folate levels. These results are suggestive of a malabsorption problem.
- The patient's medical history of Type 1 diabetes and canker sores plus her symptoms of foul smelling stool, bone loss, diarrhea, and fatigue point towards a specific disease of malabsorption: celiac disease.
- Dr. Nikolla is not surprised when an upper endoscopy reveals a flattening of the lining of the small bowel, indicative of CD. Additional blood work shows high levels of tTG (tissue transglutaminase) antibodies, a significant marker of CD. A biopsy of the small bowel adds final confirmation to the diagnosis of celiac disease when the pathologist report shows loss of villi and an increased number of lymphocytes.

## TREATMENT

Upon diagnosis of celiac disease, the patient was referred to a nutritionist for counseling on following a gluten-free diet. At her six-month follow-up, the patient states she had initial success with the diet, but now reports a recurrence of some symptoms. Blood work showing elevated levels of tTG antibodies suggests the patient has been ingesting products containing gluten.

Dr. Nikolla reminds her that the biggest challenge for celiac disease patients is dietary compliance, especially since hidden gluten exists in many products, not just wheat-based foods. With diligent dietary compliance, the patient's bowel movements return to normal. She gains weight and experiences increased energy. Her iron and vitamin levels return to normal.

# Is a Research Trial right for you?



Kimberly Secord, RN, CCRC

Patients who participate in research trials have different reasons for doing so. Some have exhausted all other treatment options, while others do it out of the goodness of their hearts and their desire to advance medicine. Still others like the special flexible scheduling, interaction with the research team and the fact that most study-related procedures—including lab work, physical exams, and imaging studies—are conducted at no cost.

unique protocols of each study, they must meet with one of Premier's clinical research staff—doctors, mid-levels, coordinators—to review the informed consent form. “These forms detail the nature of the study, the risks/benefits involved, and outline the study procedures and schedule of events that occur during the duration of the study,” she says. “During this review process, the patient has a chance to ask questions, to take the form home and discuss it with their family. The informed consent form is the most important procedure in a research trial.”

Premier Medical Group's Research Division continues to be one of the Hudson Valley's largest centers for gastroenterological and urological clinical trials. Under the leadership of principal investigators Evan Goldfischer, M.D., Medical Director for the Urology Research Division, and Peter Varunok, Medical Director for the Gastroenterology Research Division, Premier has participated in more than 250 clinical trials over the last 14 years. These studies have contributed to the approval of such drugs as Viagra, Cialis, Levitra, Detrol LA, Vesicare, Rapaflo, Mirabegron and Firmagon.

While Premier's clinical research program offers patients the opportunity to receive the newest treatments, there may be risks and side effects associated with any procedures performed and drugs investigated in the study.

Why take the chance? “Patients who participate in research trials have different reasons for doing so,” says Kimberly Secord, RN, CCRC, Premier's Clinical Research Manager. “Some have exhausted all other treatment options, while others do it out of the goodness of their hearts and their desire to advance medicine.”

Still others, she says, participate because they like the special flexible scheduling, the interaction with the research team and the fact that most study-related procedures—including lab work, physical exams, EKGs, and imaging studies—are conducted at no cost. During the course of a study, Premier's physicians and research staff are always available to answer any questions for research participants.

The willingness to participate in a trial does not, however, guarantee that a patient will be enrolled. Secord says that before patients can even begin the screening process to see if they meet the

Patients who agree to the terms of the informed consent form can then begin the study's screening process. During this phase, health histories and medications are reviewed, lab work and other tests can be conducted. “Every trial is different. Some have exclusion/inclusion protocols that are one page while others are several pages long. Some trials have screening periods that are a day, some a week, some a month,” Secord says. “We must follow the protocol for each particular study. There can be no deviation.”

The data collected is carefully reviewed and patients who meet the study's protocols will be enrolled. Some trials are “open label” studies, in which both the researchers and the patients know if they are receiving “real” medication or placebo. Others may be “double blind” studies, in which neither the researchers nor the patients know

if they are receiving “real” medication or placebo. Still others may be “single blind” studies, in which the patients do not know if they are getting medicine or placebo, but the researchers do. The frequency of patient visits with their research coordinators and doctors to dispense medications, conduct tests or lab work is based on each trial's protocols. The length of the trial may also vary as well. Some studies have a specific end-point, while others may continue for the entirety of the patient's life. Patients have the right, however, to leave a clinical trial at any time.

For some, the “unknowns” involved in a research trial may be disconcerting, but patients who do participate receive top-notch care and an extraordinary level of attention. “If we did not have research trials, we would have no advances in medical treatment that not only may benefit the patients themselves, but also the entire world of medicine,” Secord says.

**For more information about Premier's clinical research studies, please contact Kimberly Secord at 845-437-5002.**

Gastroenterology studies include treatments for Hepatitis C, Crohn's disease, ulcerative colitis, IBS (Irritable Bowel Syndrome), constipation, diarrhea, anal fissures, celiac disease, and Gastroesophageal Reflux Disorder (GERD).

Urology studies include treatments for overactive bladder, benign prostatic hyperplasia (BPH), prostate cancer, bladder cancer, kidney cancer, erectile dysfunction, female sexual dysfunction, kidney stones, hypogonadism, premature ejaculation, nocturia and vaginal atrophy.

# Premier Women's Center for Continence and Sexual Health

*Premier Women's Center for Continence and Sexual Health has been in development for some time. Over the years, we have often heard from women that they want a place where they can feel comfortable sharing private concerns regarding their health. We have also consulted with physicians frustrated by the lack of resources. A comprehensive approach was key, as patients do not want to be shuttled all over the valley to get the care they need.*

*In 2013 Premier reached the point where all the critical elements were in place so that we can provide women the comprehensive care they deserve. Whether a woman's problem is with continence, prolapse or sexual health, we now have the necessary medical, surgical and physical therapy alternatives to treat her in a single medical setting.*

---

**PremierHealth** spoke with Dr. Katz shortly after the Center opened. This is an edited version of that conversation.



Daniel Katz, MD

When I came to the community as a general urologist 17 years ago, I noticed that no one was treating the full range of women's pelvic floor and continence issues in a systematic fashion. I realized that if you did treat these concerns, and treated them successfully, you could have a significant impact on someone's life. These may not be life or death situations, but the changes possible are dramatic and more than a few patients have told me I have "given them back their life." That is a very rewarding statement for a doctor to hear.

“As I realized that there are thousands of similar patients—because women's urological problems are underdiagnosed and under-treated—I felt I could really make a difference in this community.

I started focusing on female urology, and seeking additional training to stay ahead of the curve on the latest medical, behavioral and surgical techniques. At this point, I have done thousands of vaginal surgeries—conventional, minimally invasive and robotic—and amassed a great deal of experience in the field.

WE HAVE BROUGHT TOGETHER AN OUTSTANDING STAFF with specialized training in women's health issues. One of our Nurse Practitioners, Samantha Tojino, specializes in female sexual dysfunction. Nurse Practitioner Fran Traver has extensive experience in geriatric care and is a certified biofeedback therapist. Urodynamics are performed in the center by veteran nurse Mary Kate Priest. The team is dedicated to providing a thorough, compassionate and private work-up for the

management of these very sensitive issues. We love what we do. We work hard to ensure that we partner with our patients on the path to their successful outcome.

WE HAVE COME TO THE POINT WHERE it is time to formalize our program and services to create a space, name and venue to heighten awareness and availability of these important treatments. My philosophy? Well, I approach my patients' problems with pragmatic sensitivity. I understand that this is a tough situation for them. It is embarrassing – I understand that – but I want my patients to understand they have a medical problem and we can help them. It is an awful thing for a woman to be out shopping and saturate her pants.

My staff and I are committed to the vision of a safe space where women can comfortably discuss what is going on for them and begin the road to recovery. We treat every woman like we would a family member, with respect and sensitivity, while working to remain focused and clinically precise to get them a successful



Key staff of Premier Women’s Center for Continence and Sexual Health (from left to right): Frances H. Traver, ANP-C, certified biofeedback therapist; Daniel Katz, MD; Samantha S. Tojino, FNP-C, specialist in female sexual dysfunction.

outcome. I want my patients to be able to look back on the process and say “I am cured and by the way, it was a good experience for me, too.” That is our goal.

**T**HERE HAS BEEN A TREMENDOUS RETICENCE about bringing these topics up and discussing them. Women tend to ignore these types of problems, because they are embarrassed or afraid.

For years no one spoke about erectile dysfunction. Then, with the advent of Viagra and similar drugs, men’s sexual issues became fit for primetime TV. We are just entering a similar time for women. We have come to a stage in medicine where there is beginning to be a meaningful understanding, evaluation and management of female sexual dysfunction as well. There is already a range of good treatments with successful outcomes available that can really make a big impact on women’s lives.

**The team is dedicated to providing a thorough, compassionate and private work-up for the management of these very sensitive issues. We love what we do. We work hard to ensure that we partner with our patients on the path to their successful outcome.**

**W**HAT GIVES A DOCTOR SATISFACTION is making a positive difference in someone’s life. Consider the case of a young woman who has had several children and now cannot run with her friends because every time she runs, she leaks urine into her pants, or she cannot make love to her husband for fear of leaking. When you can turn that around for somebody... you really are giving them back their life. That is what we are here for. That is why we went into medicine: to cure disease and improve our patients’ quality of life.

**I**AM VERY LUCKY. I feel privileged and honored to be able to serve in this manner. We have created a team and a center that is second to none in the Hudson valley. The space itself has a comfortable, welcoming feeling. It is soft, green and spa-like. I think it lends itself to the issues we are treating.

We are excited about sharing our vision and expertise with the women in our area. ”

“**T**here are six domains to female sexual dysfunction—desire, arousal, orgasm, lubrication, pain, satisfaction—and we treat all of them.

To a great extent, treatment involves manipulating hormone levels. When women go through menopause, for example, the hormonal changes they experience can affect them sexually; birth control pills are estrogen mediated and can decrease testosterone level, which suppresses libido; anti-depressants impact hormone levels, affecting both desire and arousal.

When we help reinstate and balance the hormones—including estrogen and testosterone—the sexual dysfunction is often overcome.

This is an exciting field. We are on the edge of major advances and already have a number of medications to prescribe for a healthier sex-life. We employ dopamine agonist therapy, which helps increase the excitatory stage. We use oxytocin, a chemical that is naturally released when people are having sexual relations, it gives that feeling of connection. We prescribe that to be taken 30 minutes prior to intimate relations, to help women in their orgasmic phase.” —Samantha Tojino, FNP-C

# Visit one of our Upper Hudson Valley Patient Service Centers

## ULSTER COUNTY

25 Grand St.  
Kingston, NY 12401  
Phone: 845-331-3106  
Fax: 845-331-3193  
Mon - Fri: 7A - 4:30P  
Sat & Sunday: closed



## ORANGE COUNTY

70 Gilbert St.  
Monroe, NY 10950  
Phone: 845-782-7222  
Fax: 845-783-4892  
Mon - Fri: 8A - 4:30P  
Sat & Sun: closed



## DUTCHESS COUNTY

334 Main St.  
Beacon, NY 12508  
Phone: 845-765-8366  
Fax: 845-765-8367  
Mon - Fri: 8A - 4:30P  
Sat & Sun: closed



27 Fox St.  
(Lower Level)  
Poughkeepsie, NY  
12601

Phone: 845-485-1067  
Fax: 845-454-3194  
Mon, Tues, Thurs & Fri:  
7A - 3:30P  
Wed: 8A - 5P  
Sat & Sun: closed



400 Westage  
Business Center  
Drive  
(Suite 210-A)  
Fishkill, NY 12524  
Phone: 845-204-9188  
Fax: 845-204-9187  
Mon - Fri: 7A - 5P  
Sat & Sun: closed



147 Lake St.  
(Basement)  
Newburgh, NY  
12550  
Phone: 845-391-8422  
Fax: 845-391-8423  
Mon - Thurs 7A - 10P  
Fri: 7A - 8P  
Sat: 9A - 5P  
Sun: 1P - 5P



## SULLIVAN COUNTY

111 Sullivan Avenue  
(Suite 2-6)  
Ferndale, NY 12734  
Phone: 845-747-9324  
Fax: 845-747-9339  
Mon - Fri:  
8:30A - 3:30P  
Sat & Sunday: closed



**BioReference**  
LABORATORIES

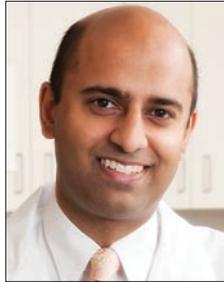


# Oasis

by BioReference Laboratories  
A New Kind of Medical Laboratory

- Coagulation Draws
- ▲ Pediatric Draws
- ♿ Handicap Accessible
- Tuberculosis Screen

# Not always what it seems



Nacem Rahman, MD

There is a general mindset that all voiding symptoms in women are UTIs. In fact, women will often come to see me and say ‘I am here because I keep getting UTIs.’ They have already given me their diagnosis without telling me their symptoms. However, it is important to realize that not all voiding complaints represent UTI’s, and if cultures suggest no bacteria and symptoms persist despite treatment, a different diagnosis needs to be entertained.

## THE CASE

A 57-year-old, post-menopausal female, referred to me by her primary care physician, presents with a 3-month history of dysuria (painful urination), frequency and urgency. Several rounds of treatment have not provided appreciable improvement, leaving her frustrated, anxious and depressed.

## REVIEWING THE CHART

The patient came to her primary care physician with a new, first-time onset of dysuria, and frequency and urgency of urination. She has had three children, all delivered vaginally. Her past medical history is significant for some mild hypertension, and hyperlipidemia. She has a remote history of tobacco use, smoking one pack per day from the age of 20 until quitting at age 42.

A pelvic exam shows some signs of atrophic vaginitis—thinning, drying and inflammation of the vaginal walls—not uncommon in postmenopausal women. A urinalysis shows 1-Plus blood (moderate microhematuria) and is positive for leukocytes. A urine culture is negative.

## TREATING FOR THE USUAL SUSPECTS

**PCP Visit 1**—On the basis of her symptoms and the presence of leukocytes—the white blood cells that fight infection—the PCP began treating for a urinary tract infection (UTI) with a prescription for Ciprofloxacin.

**PCP Visit 2**—Some three weeks later, at a follow-up visit, the patient reports no significant improvement. Repeat urinalysis and microscopy are done, and results are the same as for the first tests. The PCP continues on the assumption of the presence of a UTI and prescribes Bactrin, a different antibiotic. She also starts the patient on Estrace, an estrogen cream, which will treat the vaginitis and potentially ease some of her symptoms.

**PCP Visit 3**—At this follow-up, the patient’s symptoms are essentially unchanged, as is her third urinalysis. The physician concludes that she is not going to be successful in ridding the patient of this infection, and refers her to me.

## THE UTI MINDSET

A recent study finds that women diagnosed with genito-urinary malignancies, such as bladder and kidney cancer, are generally treated for UTIs and inflammation for a longer period of time before being referred to a urologist than are men with similar symptoms and test results.

It is true that women have a higher risk of urinary tract infections than men do, and this has led to an erroneous mindset that all voiding symptoms in woman are UTIs. In fact, women will often come to see me and say ‘I am here because I keep getting UTIs.’ They have already given me the diagnosis without giving me the symptoms.

This pervasive view of all voiding symptoms as UTIs is difficult to break, but often results in the patient being treated with several rounds of antibiotics but no change in symptoms prior to a more detailed evaluation by a urologist.

## DIAGNOSIS

We conduct our own urinalysis and pelvic examination, with results that match those of the PCP. However, given the patient’s persistent microhematuria and history of smoking, we send out for a urine cytology to check for abnormal cells, perform a CAT scan and schedule a cystoscopy.

The CAT scan is negative: the bladder has some mild thickening, but otherwise looks fine, as do the kidneys. The cytology report, however, comes back “Atypical,” meaning abnormalities were found in the cells.

During the in-office cystoscopy procedure, I examine the patient’s bladder through the lens of a cystoscope. On the left lateral wall there is a flat, patchy red area, while the remainder of the bladder appears normal. With tools introduced through the cystoscope, I perform a biopsy of the patchy area, and then cauterize it. The patient is asked to return for a follow-up in two weeks.

Lab results confirm a diagnosis of bladder cancer, specifically carcinoma in situ of the bladder (CIS). Technically, this is pre-invasive cancer, but it is considered an aggressive variant of bladder cancer. It is time to develop a treatment plan.

WHAT YOU NEED TO KNOW ABOUT

# Eosophilic Esophagitis



Arif Muslim, MD, FACC

Most people who come to the hospital emergency room with a problem swallowing or with food impaction—food trapped in the esophagus—turn out to be suffering from eosophilic esophagitis (EoE), a chronic disease not fully defined until 1993. About 40 percent of people with EoE discover they have the condition in the ER, but heartburn, chest pain, abdominal pain and vomiting are also symptoms.

Eosinophils are a type of white blood cell, part of the body's immune system. Normally, they are not present in the esophagus but become active in response to certain allergic diseases, infections, and other medical conditions. Eosinophils cause inflammation of the esophagus which, in turn, causes stiffening and narrowing of the passage.

EoE is considered to be an allergic phenomenon. Originally, it was thought to be rare in adults but, like other allergic diseases, its incidence is growing and physicians are now sensitive to its characteristic signs.

In the course of performing an endoscopy on patients with EoE, the gastroenterologist will often see linear furrows or creases in the esophagus, concentric rings in its superficial layer and white spots on the tissue.

The key to an EoE diagnosis is biopsy of several sites on the lining of the esophagus. If microscopic examination of the sample reveals a large number of eosinophils and inflammation of the tissue, eosophilic esophagitis is likely.

However, gastroesophageal reflux disease (GERD), a more common condition, can also be the cause of eosinophils in the esophagus and also has some similar symptoms. Therefore a step toward a firm diagnosis of EOE is to eliminate GERD as a cause

of the eosinophils. To that end, we generally start the patient on a weeks long course of proton-pump inhibitors (PPIs) to reduce gastric acid and suppress the symptoms of GERD. After the patient is on PPIs for some weeks, we again perform a biopsy. If excess eosinophils are found again, a diagnosis of EoE is confirmed.

Treatment of EoE is focused on controlling symptoms, reducing eosinophil levels and preventing complications of the disease, such as food impactions and pain. There are currently no FDA-approved medications for EoE. We sometimes use small doses of oral inhaled steroids to topically coat the esophagus, avoiding the side effects of systemic steroids. This reduces inflammation for a brief while.

The most significant treatment, with the longest-lasting positive effects, is dietary therapy that reduces the patient's exposure to the food, or foods, that trigger the allergic reaction behind EoE. We typically do allergy testing and try an elimination diet.

The recommended diet may be a targeted elimination of foods that registered positive in the allergy tests, or a six-food-elimination diet of the most common food allergens affecting patients with EoE: milk, soy, egg, wheat, nuts and seafood. If, after a period of time—usually about six weeks—on the elimination diet, the symptoms improve, we start reintroducing the foods, one at a time, to identify the actual culprit.

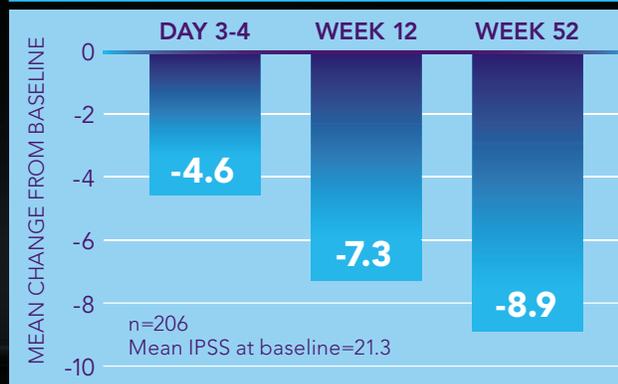
Research studies have shown that continued avoidance of the offending foods can lead to disease remission—in regard to symptoms and esophageal inflammation—for years. Controlling EoE in this fashion depends on a vigilant and motivated patient, often dieting with the support of the physician or a dietitian—if you eat the foods you are allergic to, the symptoms of eosophilic esophagitis will return.



An endoscopic view of “feline esophagus,” the concentric rings of an esophagus in the presence of eosophilic esophagitis.

# BPH SYMPTOM RELIEF THAT WORKS NIGHTS SO HE CAN WORK DAYS

## DECREASES IN IPSS\* OVER 1 YEAR<sup>1,2</sup>



Data from patients who received RAPAFLOR<sup>®</sup> for 12 weeks in a double-blind, placebo-controlled trial and for an additional 40 weeks in an uncontrolled, open-label extension study.

- Continually improves BPH<sup>†</sup> symptoms, including the irritative symptoms of nocturia, frequency, and urgency<sup>1-4‡</sup>



\*International Prostate Symptom Score.

†Benign prostatic hyperplasia.

‡Measured by reductions in the irritative subscore of the IPSS.

### IMPORTANT SAFETY INFORMATION

RAPAFLOR<sup>®</sup> is contraindicated in patients with severe renal impairment (CCr <30 mL/min), severe hepatic impairment (Child-Pugh score ≥10), with use of strong CYP3A4 inhibitors, and in patients with a history of hypersensitivity to silodosin or any of the ingredients of RAPAFLOR<sup>®</sup>.

Postural hypotension with or without symptoms (eg, dizziness) may develop when beginning treatment with RAPAFLOR<sup>®</sup>. As with all alpha-blockers, there is a potential for syncope. Patients should be warned of the possible occurrences of such events and should avoid situations where injury could result. RAPAFLOR<sup>®</sup> should be used with caution in patients with moderate renal impairment. Patients should be assessed to rule out the presence of prostate cancer prior to starting treatment with RAPAFLOR<sup>®</sup>. Patients planning cataract surgery should inform their ophthalmologist that they are taking RAPAFLOR<sup>®</sup>.

The most common side effects are retrograde ejaculation, dizziness, diarrhea, orthostatic hypotension, headache, nasopharyngitis, and nasal congestion.

Please see brief summary of full Prescribing Information on the adjacent page.

**References:** **1.** Marks LS, Gittelman MC, Hill LA, Volinn W, Hoel G. Silodosin in the treatment of the signs and symptoms of benign prostatic hyperplasia: a 9-month, open-label extension study. *Urology*. 2009;74(6):1318-1323. **2.** Data on file, Watson Laboratories, Inc. **3.** RAPAFLOR<sup>®</sup> (silodosin) Capsules full Prescribing Information, Watson Pharma, Inc. January 2013. **4.** American Urological Association. AUA guideline on management of benign prostatic hyperplasia, Revised 2010.

**Watson** 

[WWW.RAPAFLO.COM](http://WWW.RAPAFLO.COM)

Models are for illustrative purposes only.

© 2013, Watson Pharma, Inc., Parsippany, NJ 07054. All rights reserved. 09427 5/13

**RAPAFLO**<sup>®</sup> 8 mg  
(silodosin) capsules

# RAPAFLO® (silodosin) capsules

## BRIEF SUMMARY

For full Prescribing Information, see package insert.

## INDICATIONS AND USAGE

RAPAFLO, a selective alpha-1 adrenergic receptor antagonist, is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). RAPAFLO is not indicated for the treatment of hypertension.

## CONTRAINDICATIONS

- Severe renal impairment (CrCl < 30 mL/min)
- Severe hepatic impairment (Child-Pugh score ≥ 10)
- Concomitant administration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, itraconazole, ritonavir) [see *Drug Interactions*]
- Patients with a history of hypersensitivity to silodosin or any of the ingredients of RAPAFLO [see *Adverse Reactions and Description*]

## WARNINGS AND PRECAUTIONS

### Orthostatic Effects

Postural hypotension, with or without symptoms (e.g., dizziness) may develop when beginning RAPAFLO treatment. As with other alpha-blockers, there is potential for syncope. Patients should be cautioned about driving, operating machinery, or performing hazardous tasks when initiating therapy [see *Adverse Reactions and Use in Specific Populations*].

### Renal Impairment

In a clinical pharmacology study, plasma concentrations (AUC and C<sub>max</sub>) of silodosin were approximately three times higher in subjects with moderate renal impairment compared with subjects with normal renal function, while half-lives of silodosin doubled in duration. The dose of RAPAFLO should be reduced to 4 mg in patients with moderate renal impairment. Exercise caution and monitor such patients for adverse events [see *Use in Specific Populations*].

RAPAFLO is contraindicated in patients with severe renal impairment [see *Contraindications*].

### Hepatic Impairment

RAPAFLO has not been tested in patients with severe hepatic impairment, and therefore, should not be prescribed to such patients [see *Contraindications and Use in Specific Populations*].

### Pharmacokinetic Drug-Drug Interactions

In a drug interaction study, co-administration of a single 8 mg dose of RAPAFLO with 400 mg ketoconazole, a strong CYP3A4 inhibitor, caused a 3.8-fold increase in maximum plasma silodosin concentrations and 3.2-fold increase in silodosin exposure (i.e., AUC). Concomitant use of ketoconazole or other strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin, ritonavir) is therefore contraindicated [see *Drug Interactions*].

### Pharmacodynamic Drug-Drug Interactions

The pharmacodynamic interactions between silodosin and other alpha-blockers have not been determined. However, interactions may be expected, and RAPAFLO should not be used in combination with other alpha-blockers [see *Drug Interactions*].

A specific pharmacodynamic interaction study between silodosin and antihypertensive agents has not been performed. However, patients in the Phase 3 clinical studies taking concomitant antihypertensive medications with RAPAFLO did not experience a significant increase in the incidence of syncope, dizziness, or orthostasis. Nevertheless, exercise caution during concomitant use with antihypertensives and monitor patients for possible adverse events [see *Adverse Reactions and Drug Interactions*].

Caution is also advised when alpha-adrenergic blocking agents including RAPAFLO are co-administered with PDE5 inhibitors. Alpha-adrenergic blockers and PDE5 inhibitors are both vasodilators that can lower blood pressure. Concomitant use of these two drug classes can potentially cause symptomatic hypotension [see *Drug Interactions*].

### Carcinoma of the Prostate

Carcinoma of the prostate and BPH cause many of the same symptoms. These two diseases frequently co-exist. Therefore, patients thought to have BPH should be examined prior to starting therapy with RAPAFLO to rule out the presence of carcinoma of the prostate.

### Intraoperative Floppy Iris Syndrome

Intraoperative Floppy Iris Syndrome has been observed during cataract surgery in some patients on alpha-1 blockers or previously treated with alpha-1 blockers. This variant of small pupil syndrome is characterized by the combination of a flaccid iris that billows in response to intraoperative irrigation currents; progressive intraoperative miosis despite preoperative dilation with standard mydriatic drugs; and potential prolapse of the iris toward the phacoemulsification incisions. Patients planning cataract surgery should be told to inform their ophthalmologist that they are taking RAPAFLO [see *Adverse Reactions*].

### Laboratory Test Interactions

No laboratory test interactions were observed during clinical evaluations. Treatment with RAPAFLO for up to 52 weeks had no significant effect on prostate-specific antigen (PSA).

## ADVERSE REACTIONS

### Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In U.S. clinical trials, 897 patients with BPH were exposed to 8 mg RAPAFLO daily. This includes 486 patients exposed for 6 months and 168 patients exposed for 1 year. The population was 44 to 87 years of age, and predominantly Caucasian. Of these patients, 42.8% were 65 years of age or older and 10.7% were 75 years of age or older.

In double-blind, placebo-controlled, 12-week clinical trials, 466 patients were administered RAPAFLO and 457 patients were administered placebo. At least one treatment-emergent adverse reaction was reported by 55.2% of RAPAFLO treated patients (36.8% for placebo treated). The majority (72.1%) of adverse reactions for the RAPAFLO treated patients (59.8% for placebo treated) were qualified by the investigator as mild. A total of 6.4% of RAPAFLO treated patients (2.2% for placebo treated) discontinued therapy due to an adverse reaction (treatment-emergent), the most common reaction being retrograde ejaculation (2.8%) for RAPAFLO treated patients. Retrograde ejaculation is reversible upon discontinuation of treatment.

### Adverse Reactions observed in at least 2% of patients:

The incidence of treatment-emergent adverse reactions listed in the following table were derived from two 12-week, multicenter, double-blind, placebo-controlled clinical studies of RAPAFLO 8 mg daily in BPH patients. Adverse reactions that occurred in at least 2% of patients treated with RAPAFLO and more frequently than with placebo are shown in Table 1.

**Table 1 Adverse Reactions Occurring in ≥ 2% of Patients in 12-week, Placebo-Controlled Clinical Trials**

Adverse Reactions	RAPAFLO N = 466 n (%)	Placebo N = 457 n (%)
Retrograde Ejaculation	131 (28.1)	4 (0.9)
Dizziness	15 (3.2)	5 (1.1)
Diarrhea	12 (2.6)	6 (1.3)
Orthostatic Hypotension	12 (2.6)	7 (1.5)
Headache	11 (2.4)	4 (0.9)
Nasopharyngitis	11 (2.4)	10 (2.2)
Nasal Congestion	10 (2.1)	1 (0.2)

In the two 12-week, placebo-controlled clinical trials, the following adverse events were reported by between 1% and 2% of patients receiving RAPAFLO and occurred more frequently than with placebo: insomnia, PSA increased, sinusitis, abdominal pain, asthenia, and rhinorrhea. One case of syncope in a patient taking prazosin concomitantly and one case of priapism were reported in the RAPAFLO treatment group.

In a 9-month open-label safety study of RAPAFLO, one case of Intraoperative Floppy Iris Syndrome (IFIS) was reported.

### Postmarketing Experience

The following adverse reactions have been identified during post approval use of silodosin. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

Skin and subcutaneous tissue disorders: *toxic skin eruption, purpura, skin rash, pruritus and urticaria*

Hepatobiliary disorders: *jaundice, impaired hepatic function associated with increased transaminase values*

Immune system disorders: *allergic-type reactions, not limited to skin reactions including swollen tongue and pharyngeal edema resulting in serious outcomes*

## DRUG INTERACTIONS

### Moderate and Strong CYP3A4 Inhibitors

In a clinical metabolic inhibition study, a 3.8-fold increase in silodosin maximum plasma concentrations and 3.2-fold increase in silodosin exposure were observed with concurrent administration of a strong CYP3A4 inhibitor, 400 mg ketoconazole. Use of strong CYP3A4 inhibitors such as itraconazole or ritonavir may cause plasma concentrations of silodosin to increase. Concomitant administration of strong CYP3A4 inhibitors and RAPAFLO is contraindicated [see *Contraindications and Warnings and Precautions*].

The effect of moderate CYP3A4 inhibitors on the pharmacokinetics of silodosin has not been evaluated. Concomitant administration with moderate CYP3A4 inhibitors (e.g., diltiazem, erythromycin, verapamil) may increase concentration of RAPAFLO. Exercise caution and monitor patients for adverse events when co-administering RAPAFLO with moderate CYP3A4 inhibitors.

### Strong P-glycoprotein (P-gp) Inhibitors

*In vitro* studies indicated that silodosin is a P-gp substrate. Ketoconazole, a CYP3A4 inhibitor that also inhibits P-gp, caused significant increase in exposure to silodosin. Inhibition of P-gp may lead to increased silodosin concentration. RAPAFLO is therefore not recommended in patients taking strong P-gp inhibitors such as cyclosporine.

### Alpha-Blockers

The pharmacodynamic interactions between silodosin and other alpha-blockers have not been determined. However, interactions may be expected, and RAPAFLO should not be used in combination with other alpha-blockers [see *Warnings and Precautions*].

### Digoxin

The effect of co-administration of RAPAFLO and digoxin 0.25 mg/day for 7 days was evaluated in a clinical trial in 16 healthy males, aged 18 to 45 years. Concomitant administration of RAPAFLO and digoxin did not significantly alter the steady state pharmacokinetics of digoxin. No dose adjustment is required.

### PDE5 Inhibitors

Co-administration of RAPAFLO with a single dose of 100 mg sildenafil or 20 mg tadalafil was evaluated in a placebo-controlled clinical study that included 24 healthy male subjects, 45 to 78 years of age. Orthostatic vital signs were monitored in the 12-hour period following concomitant dosing. During this period, the total number of positive orthostatic test results was greater in the group receiving RAPAFLO plus a PDE5 inhibitor compared with RAPAFLO alone. No events of symptomatic orthostasis or dizziness were reported in subjects receiving RAPAFLO with a PDE5 inhibitor.

### Other Concomitant Drug Therapy

#### Antihypertensives

The pharmacodynamic interactions between silodosin and antihypertensives have not been rigorously investigated in a clinical study. However, approximately one-third of the patients in clinical studies used concomitant antihypertensive medications with RAPAFLO. The incidence of dizziness and orthostatic hypotension in these patients was higher than in the general silodosin population (4.6% versus 3.8% and 3.4% versus 3.2%, respectively). Exercise caution during concomitant use with antihypertensives and monitor patients for possible adverse events [see *Warnings and Precautions*].

#### Metabolic Interactions

*In vitro* data indicate that silodosin does not have the potential to inhibit or induce cytochrome P450 enzyme systems.

#### Food Interactions

The effect of a moderate fat, moderate calorie meal on silodosin pharmacokinetics was variable and decreased silodosin maximum plasma concentration (C<sub>max</sub>) by approximately 18 - 43% and exposure (AUC) by 4 - 49% across three different studies. Safety and efficacy clinical trials for RAPAFLO were always conducted in the presence of food intake. Patients should be instructed to take silodosin with a meal to reduce risk of adverse events.

## USE IN SPECIFIC POPULATIONS

### Pregnancy

Pregnancy Category B. RAPAFLO is not indicated for use in women.

An embryo/fetal study in rabbits showed decreased maternal body weight at 200 mg/kg/day (approximately 13-25 times the maximum recommended human exposure or MRHE of silodosin via AUC). No statistically significant teratogenicity was observed at this dose.

Silodosin was not teratogenic when administered to pregnant rats during organogenesis at 1000 mg/kg/day (estimated to be approximately 20 times the MRHE). No maternal or fetal effects were observed at this dose. Rats and rabbits do not produce glucuronidated silodosin, which is present in human serum at approximately 4 times the level of circulating silodosin and which has similar pharmacological activity to silodosin.

No effects on physical or behavioral development of offspring were observed when rats were treated during pregnancy and lactation at up to 300 mg/kg/day.

### Pediatric Use

RAPAFLO is not indicated for use in pediatric patients. Safety and effectiveness in pediatric patients have not been established.

### Geriatric Use

In double-blind, placebo-controlled, 12-week clinical studies of RAPAFLO, 259 (55.6%) were under 65 years of age, 207 (44.4%) patients were 65 years of age and over, while 60 (12.9%) patients were 75 years of age and over. Orthostatic hypotension was reported in 2.3% of RAPAFLO patients < 65 years of age (1.2% for placebo), 2.9% of RAPAFLO patients ≥ 65 years of age (1.9% for placebo), and 5.0% of patients ≥ 75 years of age (0% for placebo). There were otherwise no significant differences in safety or effectiveness between older and younger patients.

### Renal Impairment

The effect of renal impairment on silodosin pharmacokinetics was evaluated in a single dose study of six male patients with moderate renal impairment and seven male subjects with normal renal function. Plasma concentrations of silodosin were approximately three times higher in subjects with moderate renal impairment compared with subjects with normal renal function.

RAPAFLO should be reduced to 4 mg per day in patients with moderate renal impairment. Exercise caution and monitor patients for adverse events.

RAPAFLO has not been studied in patients with severe renal impairment. RAPAFLO is contraindicated in patients with severe renal impairment [see *Contraindications and Warnings and Precautions*].

### Hepatic Impairment

In a study comparing nine male patients with moderate hepatic impairment (Child-Pugh scores 7 to 9), to nine healthy male subjects, the single dose pharmacokinetics of silodosin were not significantly altered in patients with hepatic impairment. No dosing adjustment is required in patients with mild or moderate hepatic impairment.

RAPAFLO has not been studied in patients with severe hepatic impairment. RAPAFLO is contraindicated in patients with severe hepatic impairment [see *Contraindications and Warnings and Precautions*].

## OVERDOSAGE

RAPAFLO was evaluated at doses of up to 48 mg/day in healthy male subjects. The dose-limiting adverse event was postural hypotension.

Should overdose of RAPAFLO lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by maintaining the patient in the supine position. If this measure is inadequate, administration of intravenous fluid should be considered. If necessary, vasopressors could be used, and renal function should be monitored and supported as needed. Dialysis is unlikely to be of significant benefit since silodosin is highly (97%) protein bound.



Manufactured by: Watson Laboratories, Inc., Corona, CA 92680 USA

Distributed by: Watson Pharma, Inc., Parsippany, NJ 07054 USA

Under license from: Kissei Pharmaceutical Co., Ltd., Nagano, Japan

For all medical inquiries contact: WATSON Medical Communications, Parsippany, NJ 07054

800-272-5525

For additional information see:

www.rapaflo.com

or call 1-866-RAPAFLO (727-2356)

**Rx Only** Revised: January 2013

# Erectile dysfunction: When medications fail



Jaspreet Singh, DO

Although oral medications have revolutionized the treatment of ED, they do not provide a solution for every man. The PDE5 inhibitor drugs, for example, improve blood flow to the penis, but they do not impact the trapping of venous blood, which is equally important to achieving and maintaining an erection. Advances in the field now provide surgical options that offer patients who don't respond to meds a good rate of satisfaction.

Erectile dysfunction (ED) is defined as the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. It is a condition that afflicts up to 30 million American men, including half of those 40 to 70 years of age. Nearly one in every four men over the age of sixty-five will experience some degree of erectile dysfunction.

A class of medications called phosphodiesterase-5 inhibitors (PDE5) has become first line therapy for ED. Marketing for medications in this class—including Viagra, Levitra, Cialis and Staxyn—has drawn attention to the problem and the fact that there is help for it. Nevertheless, many patients and physicians find it difficult to initiate a conversation about ED during an office visit. Although ED, in and of itself, is distressing, it can also signal a serious underlying medical condition, such as cardiovascular disease. We cannot avoid the topic simply because we find it difficult to talk about.

The PDE5 inhibitors are an effective treatment for the majority of men who try them, but about 30 percent of patients fail to respond. In their case, there are several other approaches that have been successful in dealing with ED.

The least invasive treatment is the penile vacuum erection device. A vacuum cylinder is placed over the penis and a pump creates a vacuum that draws blood into the penis, causing it to become erect. A constrictive band is then positioned at the base of the shaft to maintain the erection. Studies find that, at a follow-up of 12 months, the satisfaction of both patient and partner is in the sixty percent range. The vacuum erection device is somewhat awkward to operate and not very spontaneous. The only consistent success I have seen with it

with couples in a long-term relationship. There is a limit of 30 minutes to the erection, which is not as firm as what a penile implant can provide.

The next line of therapeutic options includes the synthetic formulation of Prostaglandin E1 (PGE1), or Alprostadil. These vasodilators cause smooth muscle relaxation of blood vessels, allowing more blood flow into the penis. The medication can be administered by urethral suppository (MUSE) or by intracavernosal injection, that is, in the sides of the penile shaft (Caverject, Trimix).

Men who have success with this method report long-term satisfaction rates in the area of seventy percent. Injections may not be used more than three times a week, with an interval of 24-hours between usages. The suppository may be used no more than twice in a 24-hour period. With both methods, an erection occurs within five to 20 minutes and lasts between 30 to 60 minutes.

**Determining the causes of ED can be challenging, since most men will have multiple factors that contribute to their disease. Today, for the vast majority men with ED, and their partners, there are treatments that can lead to a more fulfilling intimate experience.**

## The implant option

A highly effective option—achieving patient and partner satisfaction rates upwards of 98 percent—is the penile implant. There are two basic types of penile prostheses—both of which are implanted during a routine outpatient procedure—flexible rod and inflatable. For most of my patients, I recommend the inflatable implant, which is completely concealed and produces a controlled, more “natural” erection, complete with orgasm and ejaculation.

The inflatable prosthesis uses hydraulic technology, with a pump filling two cylinders in the penis from a fluid reservoir. To initiate an erection, the pump (placed within the scrotum) is activated. Pressing on a deflation valve in the pump returns the penis to a normal, flaccid state.

Some men do not have the dexterity to operate the pump, and for them I may recommend the flexible implant. For this prosthesis, a pair of flexible rods is implanted in the erection chambers, producing a permanently firm penis that merely needs to be adjusted into the erect position to engage in sex.

Determining the causes of ED can be challenging, since most men will have multiple factors that contribute to their disease. Today, for the vast majority of men with ED, and their partners, there are treatments that can lead to a more fulfilling intimate experience.

[premier in the community]

# Stepping up to Leadership

The modern hospital is a complex enterprise requiring many levels of oversight. The physicians of Premier devote time and attention to helping our area hospitals set and maintain the high standards of care our patients deserve.

Listed below are some of the leadership roles we have taken on...



**Northern Dutchess Hospital, Rhinebeck**



**St. Francis Hospital, Poughkeepsie**

## GI Division Leadership Roles

### **Sunil K. Khurana, MD, FACP at Vassar Brothers Medical Center**

Trustee, Health Quest Quality & Patient Satisfaction Committee  
Trustee and past Chairman, VBMC Board of Trustees  
Trustee, VBMC Executive Committee of the Board  
Past President, Medical/Dental Staff  
Past Chief of Gastroenterology  
Past Chief of Medicine

### **Robert S. Dean, MD at Vassar Brothers Medical Center**

Secretary/Treasurer, Medical/Dental Staff  
Chairman, Credential Committee  
Member, Medical Executive Committee

### **at St. Francis Hospital**

Past Vice-President of the Medical Staff

### **Salvatore M. Buffa, MD at Vassar Brothers Medical Center**

Division Director, Gastroenterology  
Assistant Director, Internal Medicine  
Member-at-large, Medical Executive Committee,  
Member, Credentials Committee  
Member, Bylaws Committee

### **Peter M. Varunok, MD, VACP at St. Francis Hospital**

Chair, Executive Committee  
Past Secretary/Treasurer, Quality Improvement  
Past Chief of Gastroenterology  
Past Vice-Chief of Gastroenterology  
Past Secretary-Treasurer – Quality Improvement



**St. Luke's Cornwall Hospital, Newburgh**

**Arif M. Muslim, MD at St. Lukes/Cornwall Hospital**

Member, Foundation Board  
 Chairman, Credentials Committee  
 Chairman, Pharmaceutical/Therapy Committee

## Internal Medicine Division Leadership Roles

**Lorraine Nardi, MD at St. Francis Hospital**

Member, Utilization Committee

**Alan H. Gross, MD, FCCP at St. Francis Hospital**

Chairman, Pulmonary Medicine Division  
 Member, Pharmacy Committee

**Carol E. Miyake at St. Francis Hospital**

Medical Director, Center for Diabetes Management

## Urology Division Leadership Roles

**Evan R. Goldfischer, MD, MBA, FACS**

**at Vassar Brothers Medical Center**

Division Director, Urology Department  
 Member, Executive Committee  
 Medical Director, Clinical Research  
 Chairman, Institutional Review Board

**at Healthquest**

Member, Oversight Management Council

**Naeem Rahman, MD at Vassar Brothers Medical Center**

Medical Director, Robotics Program



**Vassar Brothers Medical Center, Poughkeepsie**

**Daniel Katz, MD at St. Francis Hospital**

Member, Board of Trustees  
 Member, Peer Performance Committee

**Paul Pietrow, MD at St. Francis Hospital**

Co-Director, Minimally Invasive Surgery and Robotic Surgery  
**at Northern Dutchess Hospital**  
 Co-Medical Director, Urology Department  
 Member, Quality Committee

**Scott Kahn, MD, FACS at St. Francis Hospital**

Medical Director, Urology Department  
 Member, Executive Committee  
**at Northern Dutchess Hospital**  
 Co-Medical Director, Urology Department

**Conrado Tojino, DO, FACOS at St. Luke's Cornwall Hospital**

Member, Medical Executive Committee  
 Member, Cancer Committee  
 Member, Research & Evaluation Committee

**Jaspreet Singh, DO at St. Luke's Cornwall Hospital**

Member, Operating Room Committee

**Paul Pomerantz, MD, FACS at St. Luke's Cornwall Hospital**

Past Vice President, Cornwall Hospital Staff  
 Past Member, Medical Executive Committee

**Mark Libin, MD at Vassar Brothers Medical Center**

Past Division Director, Urology Department  
**at St Francis Hospital**  
 Past Medical Director, Urology Department

**Michael Solliday, MD at Vassar Brothers Medical Center**

Past Director, Urology Division

**Kevin Torrens, R-PA, C at Vassar Brothers Medical Center**

Member, Practice Patterns Committee



**PREMIER** *medical group*

1 Columbia Street  
Poughkeepsie, New York 12601  
www.premiermedicalhv.com  
RETURN SERVICE REQUESTED

# Faces of Premier

Good healthcare requires teamwork. We are proud of the dedicated team that makes up Premier Medical Group. Their loyalty contributes to the comfort and security of our patients.

## **Paul Modica, M.D.** Anesthesiologist

*When Premier's GI division—in order to maintain complete control of our patients' endoscopic experience—started looking for an anesthesiologist to join the practice, we kept hearing good things about Dr. Paul Modica. He had over 20 years of experience, was well liked by his peers and the surgeons with whom he had worked all had very positive things to say about him.*

*We are pleased to announce that Dr. Modica joined Premier on July 1, 2013.*

**F**or many years I worked as a general anesthesiologist; now I am full-time with Premier, attending on endoscopies and colonoscopies. Here, the focus is on sedation. We need to keep the patient asleep and breathing on his or her own. In the case of an upper endoscopy, there is a scope in the patient's mouth and I am competing with the endoscopist for what we call the "airway," the respiratory area. So that is a challenge.

There is an art to it as well. We keep the patient asleep, and still and stable so the physicians can do the procedure properly. Then we want to wake the patient up quickly so they can be spoken to about the procedure and leave without duress, not sick and walking well. In a nutshell, I want to keep the patients asleep, keep them safe, and get them home.

I am comfortable with all the GI physicians. Each of them has a different rhythm to how they proceed. I have learned to adjust to that and make them and the patients happy.

I think this is an excellent group. I have worked with other GI centers, so I can tell this one is very well run; the patients are well taken care of. It is a pleasurable place to work.

