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Registration materials for the
NCS 2010 Meeting will be
mailed and available online at
www.ncsaua.org in
summer 2010!

*We look forward to seeing you in
Chicago, Illinois!*



Post-Convention News
from the

83rd Annual Meeting

November 9 - 14, 2009
Camelback Inn
Scottsdale, Arizona

Our New President by: Howard Winfield, MD



Steven Siegel, MD
President

It is a pleasure to introduce our 84th President, Dr. Steven Siegel, who has been an active member of the North Central Section for over 27 years! Steve has been involved with the Section administration in a variety of capacities including Local Arrangements Committee member and chairman, AUA Video Committee member and state representative from MN, ND and SD. His regular participation at the annual meetings includes numerous erudite lectures and presentations.

Dr. Siegel's clinical practice in the Twin Cities has focused on female urology and urodynamics. He is recognized as a national leader in these areas as well as neuromodulation of voiding dysfunction. As director of the Continence Care Center of Metropolitan Urologic Specialists, he has championed a very sought after fellowship program. Steve is an adjunct associate professor of urology at the University of Minnesota and an active contributor of many societies related to female urology and urodynamics. He is past president of the International Society of Pelvic Neuromodulation (ISPiN) and currently a board member of the Society of Urodynamics and Female Urology (SUFU).

Despite his busy clinical and academic practice, Steve and his lovely wife Carrie are avid tennis players. It might be more correct to qualify their skill level as "semi-professional" as they routinely win tennis awards at our NCS meetings. They are the proud parents of two children, Hannah (18) and David (23) who remain their pride and joy.

I have gotten to know Steve and Carrie over the past year and I know how excited and honored they are to be this year's "President and First Lady." With their sagely, graceful and gentle influence, you can expect an outstanding annual meeting both academically and socially next September 29 – October 2 in the Windy City of Chicago.

Secretary's Report

Howard N. Winfield, MD

Amongst the remarkable beauty and tranquility of the Camelback Inn and Resort in Scottsdale, Arizona, the 83rd Annual Meeting of the North Central Section was a huge success both academically and socially. Despite the difficult financial times we have lived through over the past year, the attendance was remarkably high with close to 450 registered. This is an outstanding number at an "out of section" venue and attests to the highly attractive format that has become standard for our annual meeting.

The **AUA Course of Choice**, directed by Dr. Steven Schlossberg, discussed "Urology Practice Preservation: Governance, Recruitment and Physician Phase Out." Throughout the meeting there was



Howard N. Winfield, MD
Secretary

Future Meeting

2010 84th Annual Meeting of the NCS
September 29 - October 2, 2010
Sheraton Chicago Hotel & Towers
Chicago, Illinois

an emphasis placed on healthcare management and policy changes. A highlight was the **Presidential Debate** led by NCS President Steve Nakada. On the panel were Drs. Anton Bueschen (AUA president), Lawrence Ross (AUA past president), Robert Flanigan (AUA secretary), Glenn Preminger (AUA secretary-elect) and Richard Memo (AUA treasurer). Numerous important issues were discussed and clarified for the audience by this esteemed panel.

The full gamut of urology was covered through numerous podium and poster presentations as informative panel sessions and point-counterpoint debates. Over 350 abstracts were submitted to the program committee and every effort was made to accept the very best. As has become tradition, the **NCS Resident Bowl** – Rounds #1 and #2 were highly competitive on Saturday morning leading to the determination of the “top resident” team.

The **invited speakers** were some of the “who’s who” in endourology and minimally invasive surgery. Drs. Margaret Pearle, Glenn Preminger, Dean Assimos and Ray Leveillee all gave superb lectures on important aspects of urolithiasis, endourology, ablative therapy and laparoscopic/robotic surgery. Dr. Ronald Rabinowitz gave an outstanding state-of-the-art lecture entitled “*Is Anything I Taught Dr. Nakada During His Residency About Pediatric Urology Still Valid?*” Clearly urology is a fast moving specialty, and much of what we learn in residency is only the foundation that we build on once we get out into practice.

The **honoree** this year was Dr. David Uehling who was President Nakada’s mentor and past chair of the Division of Urology at University of Wisconsin-Madison. Dr. Uehling has been a long standing and contributing supporter of the NCS. The honorary lecture was given by Dr. Margaret Pearle entitled “*Evidence Based Decision Making for Urolithiasis.*” This was followed by Dr. Nakada’s **Presidential Address**, “*The Last 20 Years of the NCS.*” What was clearly evident was the great people who have been involved with this section and who have made enormous contributions.

Besides enjoying the spectacular facilities of the Camelback Inn, the **social program**, under the guidance of local arrangements chairpersons Manoj and Mary Monga, was lively and lots of fun. The **Welcome Reception** was held in the exhibit hall with fine wine tasting and finger foods. The exhibitors truly appreciated the flow of traffic and this continues to be an important incentive for their financial support of our meeting. The **Theme Night** on Mummy Mountain included a western town atmosphere with cowboy games, steer roping and a shooting gallery. Fine barbeque dining and dancing were enjoyed by all. President Nakada and his lovely wife Deanna hosted an elegant **annual banquet** on the final evening. Dancing continued until the wee hours of the morning. Some unnamed members of the Board of Directors were also seen doing tequila shots.

The NCS Nominating Committee, chaired by Dr. Jay Hollander (past president), provided the names of Dr. Patrick McKenna for secretary-elect, Dr. Sheila Gemar for historian and Dr. Steve Nakada as alternate NCS representative to AUA Board of Directors. These positions were unanimously approved by the membership at the annual business meeting. Dr. Gary Kirsh ascended to treasurer and Dr. Peter Knapp is now president-elect. We owe Peter a huge debt of gratitude for his skillful and outstanding services to our section during his five year term as treasurer. Dr. Steve Siegel ascended to president of the section.

Special thanks are extended to the following NCS Board of Directors state representatives whose three-year terms have been completed:

Dr. Teresa Beam (Indiana)
Dr. Bernard Fallon (Iowa)
Dr. Craig Niederberger (Illinois)

We welcome the new Board of Director state representatives who are Dr. Chandru Sundarum (Indiana), Dr. Craig Block (Iowa) and Dr. Brad Schwartz (Illinois).

Other important news relates to the following items:

- 1) Eligibility requirements for membership on the Young Urologist Committee is extended to 10 years out of residency or fellowship
- 2) Due to the great success of the AUA Leadership Program, the NCS may have 3 representatives, and candidates are eligible for 15 years from the completion of residency or fellowship
- 3) The NCS AUA Foundation Scholar is Ted Skolarus who will study “Prostate Cancer Expenditures: Variations and Implications”
- 4) Approval of continued support of IVU med Scholarship

It has been an honor for me to continue to serve the membership as secretary of the North Central Section, which I consider and know it to be “**the best in the Nation.**” It was a true pleasure to work with Steve Nakada this past year during his tenure as president. Of course, the success of the meeting would not at all be possible without the incredible organization and diligence of WJ Weiser & Associates.

I encourage you all to look at your calendars and plan to join us at the **84th Annual Meeting** to be held at the Sheraton Chicago Hotel & Towers in Chicago on September 29 – October 2, 2010

From the Treasurer

Gary M. Kirsh, MD



Gary M. Kirsh, MD
Treasurer

It is an honor to assume the treasurer position for the North Central Section. The section owes a tremendous debt of gratitude to the many devoted and capable prior treasurers of the NCS, who have all collectively ensured that our section is on the finest financial footing. I would like to particularly recognize the efforts of Peter Knapp, MD. Dr. Knapp has just completed a five-year term as NCS treasurer, during which he successfully guided the Section’s finances during an almost unprecedented time of financial uncertainty in our country. We are all grateful for his efforts.

The 83rd NCS Annual Meeting was held on November 9 – 14, 2009, in Scottsdale, AZ. President Stephen Nakada, MD, Secretary

Howard Winfield, MD, and Local Arrangements Chairperson, Manoj Monga, MD, organized an outstanding academic meeting with many state-of-the-art presentations, panel discussions, and resident paper presentations. By all measures the meeting was a success for participants, as the NCS Board continues to explore new avenues to provide additional value to NCS members and meeting attendees.

Dr. Knapp presented the Treasurer's Report to the Finance Committee, Board of Directors, and membership at the Annual Business Meeting. Year-end 2008 audited financial statements and mid-year, (9/30/09), financial reports were presented. The 2008 Annual Meeting raised a record amount of \$602,026 and was successful both financially and academically. In 2008, the Educational Fund decreased by \$723,308 due to a net market loss on investments.

Preliminary 2009 year-end financial statements reflect a fund balance of \$2,337,570 with an operating surplus of \$195,918 for the year. Cash held in the Merrill Lynch operating account totaled \$197,925 and the balance in the Education Fund totaled \$2,124,454.

The Educational Fund performance was up 24.07% for the past year. Long-established NCS board guidelines of 40% – 60% equities, 20% – 40% fixed income, and 0% – 20% cash are being maintained. The Education Fund currently maintains a slight overweight in cash, which has been beneficial in the recent down market. Other expenses of the Education Fund are \$10,000 for the AFUD Research Scholar Program, \$87,000 for Resident Rebate expenses and \$18,000 for Resident Scholarships. The annual meeting had a surplus of \$35,618. This surplus combined with the investment income and dues help offset operating expenses for the year.

I anticipate an exciting and successful 2010 for the NCS under the leadership of our president, Dr. Steven Siegel. I look forward to seeing each of you at our annual meeting this fall in Chicago.

Report from the Immediate Past President

Stephen Y. Nakada, MD



Stephen Y. Nakada, MD
Immediate
Past President

What a wonderful week we had in Scottsdale! Deanna, Sarah and I had an exhilarating time from start to finish. The weather was spectacular, and Dr. Howard Winfield crafted a superb academic program that was appreciated by all. I want to personally thank our invited lecturers, Steven Schlossberg, Dean Assimos, Ron Rabinowitz, Glenn Preminger Margaret Pearle, and Ray Leveillee. They were all terrific! Moreover, the President's Debate was so enthralling that Bob Flanigan is planning to publish the discussion in the *AUA News*.

The social events were special. From welcoming ceremonies in the exhibit area, to a great evening at Mummy Mountain, to the Friday

night banquet and evening that carried on longer than any we can remember, our social programs were well attended and most convivial. Many thanks go to our wonderful local arrangements couple, Manoj and Mary Monga. And last but not least, WJ Weiser & Associates again delivered a meeting beyond our expectations, and all under budget!

My heartiest congratulations to Pat McKenna, our secretary-elect, and Sheila Gemar, our new historian. I would also like to thank Peter Knapp, who finished his term as treasurer at the meeting in Scottsdale. We are so blessed to have such wonderful people willing to serve our great section! Deanna and I are most pleased to hand the reigns to Steven and Carrie Siegel, who will be spectacular in the role of the presidency this year. We are most excited to return to Chicago in September 2010.

All in all, 14 past presidents attended the meeting, as well as current and past AUA presidents, AUA officers, and of course many of the members and residents of our great section. I cannot thank you all enough for making the 83rd NCS meeting most memorable. As I look towards our future, the North Central is most healthy, even in such uncertain times for healthcare. I truly believe that the dedication of our leadership, the strength of our membership, and the great infrastructure provided by WJ Weiser & Associates will lead us down the right path in the years to come. Hope you had a great holiday season and see you all in Chicago!

State Affairs Update

Matt Swentkofske

Manager, State Government Affairs

Lawmakers returned from their holiday break in early January for the start of legislative sessions that will focus on state budgets and economic development with an eye towards the 2010 fall elections. 2010 regular legislative will commence in early January in Indiana, Ohio, Iowa, Illinois, Michigan, South Dakota and Wisconsin. Minnesota's legislature will begin in early February and North Dakota will not meet in 2010.

Enacting any health policy bill with fiscal implications in NCS section states will be quite difficult due to budgetary challenges states face. A Pew Research Center report from early this year lists numerous NCS states as facing a severe budgetary crisis. Illinois, Michigan and Wisconsin are among the top ten states facing the worst combination of foreclosure rates, jobless numbers, state revenue losses, budget gaps, and huge obstacles to future balanced budgets. So enacting sweeping state healthcare policy reforms are not among the top priorities. Nevertheless, health policy legislation will appear that NCS members must monitor to gauge its impact on your patients. Here are a few bills to watch in every state.

Iowa

Senate Study Bill 1201 will look into how the Iowa certificate of need (CON) process can better handle contested and uncontested applications, and applications relating to institutional health facilities in rural areas. Reforming this process the right way will make it easier for urologists to expand services and facilities to better serve patients.

Illinois

Senate Bill 1617 will make changes to the state laws regarding who can perform advanced diagnostic imaging and who is served by ambulatory surgery centers (ASCs). This bill will mandate that in order for imaging centers and ASCs to obtain or renew their state license then it must meet charity care requirements (that hospitals already meet) and that the institution cannot refuse patients based on Medicaid eligibility. Enacting these laws will change how urologists both serve and treat existing and new patients.

Indiana

House Bill 1526 requires the state health commissioner to designate a hospital as a specialty hospital or a non-specialty hospital upon issuance or renewal of the hospital's license. It also requires ambulatory surgical centers to report specified information to the Indiana State Department of Health (ISDH). It also prohibits a physician with ownership interest in a specialty hospital or ambulatory surgical center from making certain patient referrals to that hospital or center. Making this change will affect how urologists refer patients to other facilities.

Michigan

Although thoroughly defeated during the state budget process earlier this year, **Senate Bill 854 and House Bill 5386** are still in their respective committees and if passed would impose a three percent tax on the gross income of physicians. A tax of this magnitude would unfairly target providers and cause a mass exodus of doctor's from Michigan.

Minnesota

Minnesota **House Bill 1027** will allow patients to enter into private contract with providers to cover the total cost of care. It will repeal the current prohibition on balance billing for Medicare patients. Repealing this ban, would allow providers to be paid equal to what it costs to treat patients.

North Dakota

The North Dakota legislature will not convene in 2010.

South Dakota

At time of publication, no single piece of legislation directly affecting urology had been introduced in South Dakota.

Ohio

House Bill 134 will mandate that companies providing insurance for basic healthcare services in Ohio shall offer to provide, as a supplemental healthcare service benefits to its subscribers, for the expenses of examinations and laboratory tests for prostate cancer screening. Legislation focuses on providing coverage for PSA screening will allow more men to be examined by their urologists.

Ohio **House Bill 205** will require hospitals and ambulatory surgical facilities to assign a circulating nurse to each procedure performed in an operating room or invasive procedure room and to require surgical technologists to work under the direct supervision of circulating nurses. This change will increase the cost of services to an ASC patient without a corresponding increase in patient safety.

Wisconsin

Wisconsin **Senate Bill 218** requires a healthcare provider to disclose to a consumer the provider's median billed charge for a healthcare

service, diagnostic test, or procedure, upon request from the patient. It also requires a healthcare provider to disclose specified charge information for the 25 presenting conditions for which the provider most frequently provides services, as identified by the state. It further stipulates that providers display a sign that informs patients of their right to receive charge information from the healthcare providers and from their insurers.

NCS Awards 2009 – Scottsdale, Arizona

Traveling Fellowship Award

Michael Large, MD

Thirlby Award

Peter Knapp, MD, Ronald Suh, MD

Bizarre & Interesting Case Award

Anthony Polcari, MD

John D. Silbar Award

Brian Lane Gallagher, MD (Iowa Clinics)

Exhibitor Drawing

3 rd	\$50.00	Jay Blind, Astellas Pharma US
2 nd	\$75.00	Marco Wohnig, Richard Wolf
1 st	\$100.00	Katie Hire, sanofi-aventis

Physician Drawing

\$500.00	Irving S. Garlovsky, MD
\$400.00	Peter A. Holoch, MD
\$300.00	Edward Mannix, PhD
\$200.00	Srinivas Vourghanti, MD
\$100.00	Howard J. Korman, MD

Quiz Bowl Winners

1st Place Team:

Christina B. Ching, MD (Cleveland Clinic)
Paul R. Tonkin, MD (Medical College of Wisconsin)
Peter A. Holoch, MD (University of Iowa)
Don T. Bui, MD (William Beaumont Hospital)

2nd Place Team:

Youssef S. Tanagho, MD, MPH (Case Western Reserve)
Matthew J. Mellon, MD (Indiana University)
Scott D. Shie, MD (NEOUCOM)
Sundeep Deorah, MD (University of Cincinnati)

Tennis Winners

Steven Siegel (Men's)
Carrie Siegel (Women's)

Abbott Laboratories
Accuray Incorporated
Allergan
American Medical Systems
American Urological Association
Ameripath
Amgen, Inc.
Astellas Pharma US, Inc.
Aureon Labs
Auxilium Pharmaceuticals, Inc.
Avero Diagnostics
Boston Scientific
Calypso Medical
CBL Path
Coloplast
Cook Medical
Covidien/Liebel Flarsheim
Dendreon Corporation
Endo Pharmaceuticals
Ethicon Women's Health & Urology
Ferring Pharmaceuticals
Galil Medical
Genesis HealthCare System
GTx, Inc.
HealthTronics
Intuitive Medical Software
Intuitive Surgical, Inc.
Karl Storz Endoscopy-America
Know Error
Lisa Laser USA
Lumenis, Inc.
Medispec, Ltd.
Medtronic, Inc.
Meridian EMR, Inc.
Novartis Pharmaceuticals
Oceana Therapeutics, Inc.
Olympus/Gyrus ACMI
Ortho Women's Health
OUR Lab
Path Group
PercuVision LLC
Pfizer, Inc.
Richard Wolf Medical
sanofi-aventis
United Medical Systems
University Compounding Pharmacy
Urologix, Inc.
Uroplasty, Inc.
Vision Sciences, Inc.
Watson Pharma, Inc.

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Necrology Report 2009

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Mark your calendars now!

NCS 84th Annual Meeting
September 29 – October 2, 2010
Sheraton Chicago Hotel & Towers
Chicago, Illinois

**Registration materials for the NCS 2010 Annual Meeting will be mailed and available online at www.ncsuaa.org in summer 2010!
We look forward to seeing you in Chicago, Illinois!**

For a difference in dryness

Start and stay with VESicare

Important Safety Information

VESicare tablets are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. The recommended dose of VESicare is 5 mg once daily. If the 5-mg dose is well tolerated, the dose may be increased to 10 mg once daily.

As with other anticholinergic agents, VESicare is contraindicated in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, and in patients with hypersensitivity to the product.

As with other anticholinergic agents, VESicare should be administered with caution to patients with bladder outflow obstruction, decreased gastrointestinal motility, controlled narrow-angle glaucoma, or reduced renal or hepatic function. Doses of VESicare higher than 5 mg are not recommended in patients with severe renal impairment, moderate hepatic impairment, or when administered with ketoconazole or other CYP3A4 inhibitors. Use of VESicare in patients with severe hepatic impairment is not recommended.

In placebo-controlled studies, the most common adverse events reported by patients were dry mouth (10.9%, 27.6%, 4.2%), constipation (5.4%, 13.4%, 2.9%), blurred vision (3.8%, 4.8%, 1.8%), and dyspepsia (1.4%, 3.9%, 1.0%), with VESicare 5 mg, 10 mg, and placebo, respectively.

The overall rate of serious adverse events was 2%. For the 10-mg dose, three intestinal serious adverse events were reported (one fecal impaction, one colonic obstruction, and one intestinal obstruction). For the 5-mg dose, one case of angioneurotic edema was reported.

Please see brief summary of Prescribing Information on the following page.

For more information, visit www.VESicare.com.

VESicare
(solifenacin succinate)
tablets



VESIcare®

(solifenacin succinate) Tablets

BRIEF SUMMARY OF PRESCRIPTION INFORMATION

Please see full Prescribing Information for complete product information.

INDICATIONS AND USAGE

VESIcare is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency.

CONTRAINDICATIONS

VESIcare is contraindicated in patients with urinary obstruction, gastric obstruction, uncontrolled narrow-angle glaucoma, and in patients who have demonstrated hypersensitivity to the drug substance or other components of the product.

PRECAUTIONS

Bladder Outflow Obstruction

VESIcare, like other anticholinergic drugs, should be administered with caution to patients with clinically significant bladder outflow obstruction because of the risk of urinary retention.

Concomitant Medication Interactions and Increased GI Motility

VESIcare, like other anticholinergics, should be used with caution in patients with decreased gastrointestinal motility.

Controlled Narrow-Angle Glaucoma

VESIcare should be used with caution in patients being treated for narrow-angle glaucoma. (See CONTRAINDICATIONS)

Reduced Heart Function

VESIcare should be used with caution in patients with reduced heart function. Doses of VESIcare greater than 5 mg are not recommended in patients with severe renal impairment ($CL_{CR} < 30$ mL/min). (See CLINICAL PHARMACOLOGY section of full Prescribing Information, DOSAGE AND ADMINISTRATION)

Reduced Hepatic Function

VESIcare should be used with caution in patients with reduced hepatic function. Doses of VESIcare greater than 5 mg are not recommended in patients with moderate hepatic impairment (Child-Pugh B). VESIcare is not recommended for patients with severe hepatic impairment (Child-Pugh C). (See CLINICAL PHARMACOLOGY section of full Prescribing Information, DOSAGE AND ADMINISTRATION)

Drug-Drug Interactions

Do not exceed a 5 mg daily dose of VESIcare when administered with therapeutic doses of lorazepam or other potent CYP3A4 inhibitors. (See CLINICAL PHARMACOLOGY section of full Prescribing Information, DOSAGE AND ADMINISTRATION)

Patients with Obstructed or Impaired QT Prolongation
In a study of the effect of solifenacin on the QT interval in 76 healthy women (See CLINICAL PHARMACOLOGY section of full Prescribing Information, Cardiac Electrophysiology), the QT prolonging effect appeared less with solifenacin 50 mg than with 20 mg (three times the maximum recommended dose), and the effect of solifenacin 20 mg did not appear as large as that of the positive control mifepristone at its therapeutic dose. This observation should be monitored in clinical studies to provide VESIcare for patients with a known history of QT prolongation or patients also on taking medications known to prolong the QT interval.

Information for Patients

Patients should be informed that anticholinergic agents such as VESIcare have been associated with constipation and blurred vision. Patients should be advised to contact their physician if they experience severe abdominal pain or become constipated for 3 or more days. Because VESIcare may cause blurred vision, patients should be advised to exercise caution in activities to engage in primarily dangerous activities until the drug's effect on the patient's vision has been determined. Heat protection (due to decreased sweating) may occur when anticholinergic drugs, such as VESIcare, are used in a hot environment. Patients should read the patient leaflet entitled "Patient Information VESIcare" before starting therapy with VESIcare.

Reproductive, Maternal, Impairment of Fertility
Solifenacin succinate was not mutagenic in the *in vitro* Salmonella typhimurium or Escherichia coli mutagenicity

assays. In the *in vivo* micronucleus test in human peripheral blood lymphocytes, with or without metabolic activation, or in the *in vivo* micronucleus test in rats.

No increase in tumors was found following the administration of solifenacin succinate to male and female rats for 904 weeks at doses up to 200 mg/kg/day (5 and 11 times human exposure at the maximum recommended human dose [MRHD], respectively), and male and female rats for 904 weeks at doses up to 20 and 15 mg/kg/day, respectively (<1 times exposure at the MRHD).

Solifenacin succinate had no effect on reproductive function, fertility or early embryonic development of the fetus in male and female rats treated with 250 mg/kg/day (7.5 times exposure at the MRHD) of solifenacin succinate, and in male rats treated with 50 mg/kg/day (<1 times exposure at the MRHD) and female rats treated with 100 mg/kg/day (1.7 times exposure at the MRHD) of solifenacin succinate.

Pregnancy, Teratogenic Effects, Pregnancy Category

Pregnancy Category C

Reproductive studies have been performed in rats, rabbits, and monkeys. After oral administration of ¹⁴C-solifenacin succinate to pregnant rats, drug-related material was shown to cross the placental barrier. No embryotoxicity or teratogenicity was observed in rats treated with 30 mg/kg/day (1.2 times exposure at the maximum recommended human dose [MRHD]). Administration of solifenacin succinate to pregnant rats, at doses of 300 mg/kg and greater (2.6 times exposure at the MRHD), during the major period of organ development resulted in reduced fetal body weights. Administration of 250 mg/kg (7.5 times exposure at the MRHD) to pregnant rats resulted in an increased incidence of club fetuses. In mice and fetal rabbits exposed to maternal doses of solifenacin succinate of 300 mg/kg/day and greater (2.6 times exposure at the MRHD) resulted in reduced pup weight and postnatal survival, reduction in body weight gain, and delayed physical development (eye opening and vaginal patency). An increase in the percentage of male offspring was also observed in litter sizes slightly reduced to maternal doses of 250 mg/kg/day. No embryotoxic effects were observed in rats at up to 50 mg/kg/day (<1 times exposure at the MRHD) or in rabbits at up to 50 mg/kg/day (1.3 times exposure at the MRHD). There are no adequate and well-controlled studies in pregnant women. Because animal reproductive studies can not always predict for human response, VESIcare should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery

No effect of VESIcare on labor and delivery in humans has not been established.

There were no effects on natural delivery in rats treated with 20 mg/kg/day (1.2 times exposure at the maximum recommended human dose [MRHD]). Administration of solifenacin succinate at 100 mg/kg/day (2.6 times exposure at the MRHD) or greater increased pup weight, pup survival, and delays in the onset of reflex and physical development during the lactation period.

Nursing Mothers

After oral administration of ¹⁴C-solifenacin succinate to lactating rats, radioactivity was detected in maternal milk. There was no adverse observation in rats treated with 20 mg/kg/day (1.2 times exposure at the maximum recommended human dose [MRHD]). Pups of female rats treated with 300 mg/kg/day (2.6 times exposure at the MRHD) or greater showed reduced body weights, pup survival, and delays in the onset of reflex and physical development during the lactation period.

It is not known whether solifenacin is excreted in human milk. Because many drugs are excreted in human milk, VESIcare should not be administered during nursing. A decision should be made whether to discontinue nursing or to discontinue VESIcare in nursing mothers.

Pediatric Use

No safety and effectiveness of VESIcare in pediatric patients has not been established.

Geriatric Use

In placebo-controlled clinical studies, similar safety and effectiveness were observed between older (≥65 years) and younger patients (1388 patients <65 years) treated with VESIcare. (See CLINICAL PHARMACOLOGY section of full Prescribing Information, Pharmacokinetics in Special Populations)

ADVERSE REACTIONS

VESIcare has been evaluated for safety in 1811 patients in randomized, placebo-controlled trials. Expected side effects of anticholinergic agents are dry mouth, constipation, blurred vision (accommodation disturbances), urinary retention, and dry eyes. The most common adverse events reported in patients treated with VESIcare were dry mouth and constipation and the incidence of these side effects was higher in the 30 mg compared to the 5 mg dose groups. In the four 12-week double-blind clinical trials, there were three identical serious adverse events in patients, all treated with VESIcare 30 mg (one fecal impaction, one colonic obstruction, and one intestinal obstruction). The overall rate of serious adverse events in the double-blind trials was 2%. Adverse events were less frequent in one patient taking VESIcare 5 mg. Compared to baseline levels of treatment with VESIcare, the incidence and severity of adverse events were similar in patients who switched on day 14 up to 12 weeks. The most frequent reason for discontinuation due to an adverse event was dry mouth, 1.5%. Table 1 lists adverse events, regardless of causality, that were reported in randomized, placebo-controlled trials at an incidence greater than placebo and in 5% or more of patients treated with VESIcare 5 or 30 mg were daily for up to 12 weeks.

Table 1. Percentage of Patients with Treatment-Related Adverse Events Exceeding Placebo Rate and Reported by 5% or More Patients for Double-Blind Placebo Studies

SYSTEM ORGAN CLASS MedDRA Preferred Term	Placebo (%)	VESIcare 5 mg (%)	VESIcare 10 mg (%)
Number of Patients	1216	570	1333
Number of Patients with Treatment-Related AEs	624	295	773
GASTROINTESTINAL DISORDERS			
Dry Mouth	4.2	10.9	27.6
Constipation	2.9	5.4	13.4
Nausea	2.0	3.7	3.3
Dyspepsia	3.0	3.4	3.9
Abdominal Pain Upper	3.0	3.9	3.2
Vomiting NOS	0.9	0.2	1.1
INFECTIONS AND INFESTATIONS			
Urinary Tract Infection NOS	2.8	2.8	4.8
Vaginitis	1.3	2.2	0.9
Pharyngitis NOS	1.0	0.3	1.1
NERVOUS SYSTEM DISORDERS			
Dizziness	3.8	3.9	3.8
EYE DISORDERS			
Vision Blurred	3.8	3.6	4.8
Dry Eyes NOS	0.6	0.3	1.6
RENAL AND URINARY DISORDERS			
Urinary Retention	0.6	0	1.4
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			
Edema Lower Limb	0.7	0.3	1.1
Fatigue	1.1	1.0	2.1
PSYCHIATRIC DISORDERS			
Depression NOS	0.8	1.2	0.8
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			
Cough	0.2	0.2	1.1
MUSCULAR DISORDERS			
Hypertension NOS	0.6	1.4	0.6

POST-MARKETING SURVEILLANCE

The following events have been reported in association with solifenacin use in controlled post-marketing surveillance: Genetec postural edema, hypersensitivity reactions, including angioedema, rash, pruritus, and urticaria; Central Nervous System disorders, including dizziness, drowsiness, QT prolongation; Fracture of Femur; Because these spontaneously reported events are from the worldwide post-marketing surveillance, the frequency of events and the role of solifenacin in their causation cannot be reliably determined.

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