

Toviaz®
(fesoterodine fumarate)

**Don't Let Overactive Bladder Stop You In
Your Tracks...**



James Ahearn, Michelle Miller, Casey Murdock, Michelle
Shemkovitz, Ben Yudin



What is Overactive Bladder?

- Urgency: having a strong need to urinate right away
- Frequency: having to urinate often
- Urgency incontinence: involuntary loss of urine
- Nocturia: waking up > 2 times

Source: International Continence Society



OAB Prevalence

200 million people globally

33 million men and women in the U.S.

1 in every 6 persons who are over the age of 40

Source: Global Industry Analysts



OAB Treatment

First Line Therapy

Behavioral therapy; physical therapy; lifestyle changes

Bladder training, pelvic floor muscle therapy, change in diet

Prescription Medication

Detrol LA, Enablex, Vesicare, Sanctura, Botox, Ditropan XL

Similar results in terms of safety and efficacy

Half of patients stop taking medication

Source: Consumer Reports



OAB Market Growth

GlobalData

- Market worth \$1.8 billion in 2011
- Market worth \$1.3 billion in 2019

Patent Expires of key drugs

Source: RegenceRx Pharmacy Benefit Management



Current Trends

Increased awareness

- OAB as an under diagnosed condition

 - Women wait 6.5 years for diagnosis

 - 2/3 of men and women never discuss their symptoms of OAB with their doctor

Aging population

Development of novel drugs

- Past unmet needs

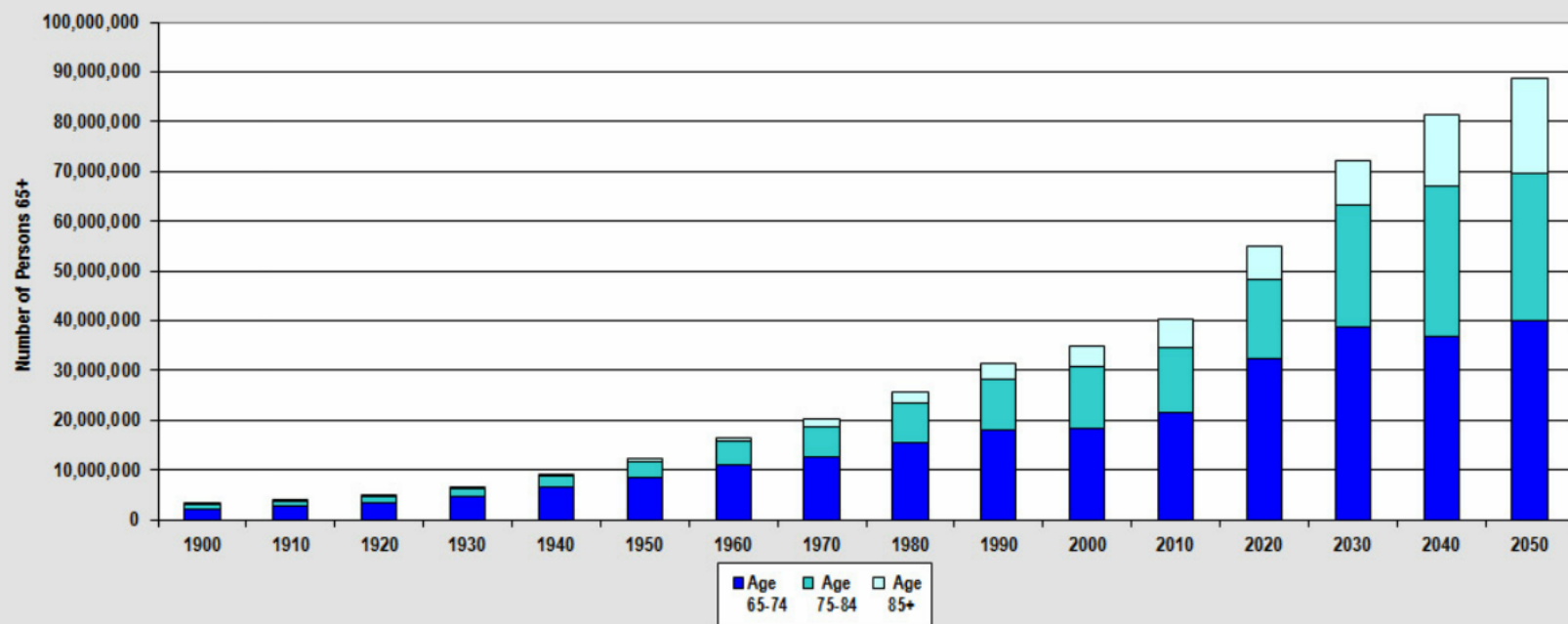
 - Common side effects and inability of drugs to offer complete compliance

Source: Global Industry Analysts



Population 65+ by Age: 1900-2050

Source: U.S. Bureau of the Census



OAB Market Prescriptions

Oxybutynin 27.3%

VESIcare 24.4%

Oxybutynin ER 18.8%

Detrol LA 12.7%

Enablex 6.5%

Toviaz 4.2%

Source: IMS Health; Vector One: National; January 2012



OAB Market Promotional Spending

VESIcare 44.8%

Toviaz 37.7%

Enablex 11.8%

Sanctura XR 2%

Others 3.7%

Source: IMS Health; Integrated Promotional Services; MAT 11/11



Clinical Trials

Testing the Efficacy of Toviaz in doses of 4mg and 8mg

12 week Phase 3 randomized, double-blind placebo controlled study

Mean age 58

79% female

21% male



Clinical Trial Findings..

- Compared to the placebo Toviaz had statistically significant reductions in the number of urges per 24 hours
- Using 4-point scale ranging from “Improved” to “Greatly Improved”
 - Toviaz scored higher than placebo



Clinical Trial #2

- Open label extension study
- Phase 3 designed to assess long term safety, tolerability and maintenance of Toviaz therapy in adults with OAB
- 12 week, short term, double blind study
- Started with 8 mg, lowered to 4mg after 1 month
- Efficacy was measured up to 2 years, safety/tolerability up to 3 years
- Study was never finished, it was terminated by Schwarz Pharma





SWOT Analysis



Strengths

- Pfizer offers patient assistant programs to help people who cant afford the medication
- Toviaz taken only once per day; with or without food
- Toviaz 8mg has proven superiority vs. Detrol LA 4mg in reducing urge urinary incontinence

1. Pfizer for professionals



Weaknesses

- Newest OAB drug on the market (there is limited research to date)
- Cost
- Does not offer any safety advantages over other treatment options
- Compliance; patients taking it at the same time everyday
May take up to 12 weeks to feel full benefits
- Many harmful side effects...Why would someone switch?



Opportunities

Gives physicians a new option to address challenges OAB patients face

Threats

Sanctura has proven less severe side effects including a lower rate of dry mouth among this patients

Does not provide additional value in terms of efficacy, safety, convenience or cost





Target Market and Objectives



Women ages 55-85
Physicians



Increase awareness of OAB through consumer
marketing and promotional efforts

Increase physician visits to talk about OAB

Increase amount of Toviaz prescriptions through
professional marketing (e-detailing, detail aids)



Campaign Theme



“Don’t Let Overactive Bladder Stop You In Your Tracks”

- OAB does not have to stop you from living life to the fullest.
- Each ad, commercial and detail aid will portray an older couple enjoying the outdoors- without having to worry about where the nearest restroom is.





- Brand Colors

- Positioning

“Toviaz is the latest treatment option for patients suffering from overactive bladder and the 8mg dosage has proven superiority vs. Detrol LA 4mg in reducing urge urinary incontinence.”





Advertising Plan: Creative



[Home](#) [About OAB](#) [Symptoms Quiz](#) [Safety & Side Effects](#) [More](#)



Don't Let Over Active Bladder Stop You In Your Tracks...

About Toviaz®

Do you find yourself constantly wondering where the closest restroom is? Does going to the bathroom consume the majority of your day? One Toviaz (fesoterodine fumarate) pill a day is clinically proven to reduce overactive

The Toviaz® Plan

Toviaz comes with *YourWay*, a complete plan of smart dietary choices and behavioral techniques to reduce overactive bladder symptoms. Learn more about the pill with a

Talk to Your Doctor

Take our OAB symptoms quiz and talk to your doctor if you think you experience any symptoms of overactive bladder. The more you say the better your doctor can prescribe the right treatment. Learn more about how to start

About Toviaz®

Do you find yourself constantly wondering where the closest restroom is? Does going to the bathroom consume the majority of your day? One Toviaz (fesoterodine fumarate) pill a day is clinically proven to reduce overactive bladder (OAB) symptoms such as leaks, strong sudden urges to go, and going too often. Learn more about how Toviaz works....

[More info](#)

The Toviaz® Plan

Toviaz comes with *YourWay*, a complete plan of smart dietary choices and behavioral techniques to reduce overactive bladder symptoms. Learn more about the pill and a plan...

[More info](#)

Talk to Your Doctor

Take our OAB symptoms quiz and talk to your doctor if you think you experience any symptoms of overactive bladder. The more you say the better your doctor can prescribe the right treatment. Learn more about how to start the conversation and tips for talking with your doctor...

[More info](#)

Stop Worrying and Start Living!



Important Safety Information: If you have certain stomach problems or glaucoma you should not take Toviaz®.

The most common side effects are dry mouth and constipation.

TESTIMONIAL

"With once a day Toviaz I no longer have to worry about finding the next restroom. I can finally enjoy life and do the things I love without the constant need to go."

Mary Smith

Copyright © 2012 Pfizer Inc. All rights reserved. Pfizer, PO Box 29387, Mission, KS 66201



Did You Know...

The OAB Symptoms Quiz can help you better explain your symptoms to your doctor.



Get Doctor Conversation Tips

Talking with your doctor about your OAB symptoms isn't easy. But he or she is the only one who can make a diagnosis. Use this link to download conversation tips and a guideline to initiating a discussion with your doctor. If your doctor says that you have OAB, you can ask if Toviaz may be right for you.



Find a Doctor in your area

The American Medical Association (AMA) offers a search tool on its Website. Search for doctors by name, or medical speciality along with city, state and zip.



Keep a one-day bladder diary

Keep a written diary of your daily bladder habits to help your doctor better understand your symptoms. Remember to bring it with you next time you visit your doctor's office.

Don't Let Overactive Bladder Stop You In Your Tracks...



Indication & Clinical Use

Indicated for the treatment of patients with overactive bladder with symptoms of urinary frequency, urgency, or urge incontinence, or any combination of these symptoms.

Different by Design

- The conversion of TOVIAZ to its active metabolite 5-HMT is not dependent on cytochrome P450 live enzyme

Demonstrated Efficacy in treating OAB symptoms

- Up to 5x decrease in urgency episode/24 hrs
 - Vs placebo at Week 12
 - Median % change from baseline: -16.35 % TOVIAZ 4 mg and -18.4 % TOVIAZ 8mg vs. -3.3% placebo.

Common Side Effects

Dry mouth and constipation

Important Safety Information

TOVIAZ tablets should be used with caution in patients with clinically significant bladder outlet obstruction, decreased gastrointestinal motility, controlled narrow-angle glaucoma, or myasthenia gravis.

The recommended starting dose of TOVIAZ is 4 mg once daily swallowed whole. Based upon individual response and tolerability, the dose may be increased to 8 mg once daily. Doses greater than 4 mg are not recommended in patients with severe renal insufficiency, or in patients taking a potent CYP3A4 inhibitor. TOVIAZ is not recommended for use in patients with severe hepatic impairment (Child-Pugh C).

For More Information

Please consult the product monograph at www.toviaz.com for important information relating to adverse reaction, drug interactions, and dosing information which have not been discussed.



Toviaz is a registered trademark of Pfizer Inc.



Don't Let OAB Stop You In You Tracks

Indications and Usage: Toviaz® is a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

TOVIAZ



**Introducing Toviaz.
The Newest form of
treatment for Over-
active Bladder
Symptoms**

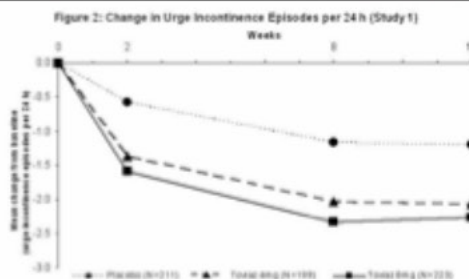
Clinical Trials Experience: The safety of Toviaz was evaluated in Phase 2 and 3 controlled trials in a total of 2859 patients with overactive bladder, of which 2288 were treated with fesoterodine. Of this total, 782 received Toviaz 4 mg/day, and 785 received Toviaz 8 mg/day in Phase 2 or 3 studies with treatment periods of 8 or 12 weeks. Approximately 80% of these patients had >10 weeks exposure to Toviaz in these trials. In Phase 2 and 3 placebo-controlled trials combined, the incidences of serious adverse events in patients receiving placebo, Toviaz 4 mg, and Toviaz 8 mg were 1.9%, 3.5%, and 2.9%, respectively. All serious adverse events were judged to be not related or unlikely to be related to study medication by the investigator, except for four patients receiving Toviaz who reported one serious adverse event each: angina, chest pain, gastroenteritis, and QT prolongation on ECG.

Important Safety Information: Angioedema of the face, lips, tongue, and/or larynx has been reported with fesoterodine, in some cases after the first dose. Patients should be advised to promptly discontinue fesoterodine therapy and seek immediate medical attention if they experience edema of the tongue, laryngopharynx, or difficult breathing.

TOVIAZ tablets should be used with caution in patients with clinically significant bladder outlet obstruction, decreased gastrointestinal motility, controlled narrow-angle glaucoma, or myasthenia gravis.

TOVIAZ is associated with anticholinergic central nervous system (CNS) effects including headache, dizziness, and somnolence. Advise patients not to drive or operate heavy machinery until they know how TOVIAZ affects them.

**In the placebo-controlled registration study at Week 12
TOVIAZ significantly reduced urge urinary incontinence^{1,2}**

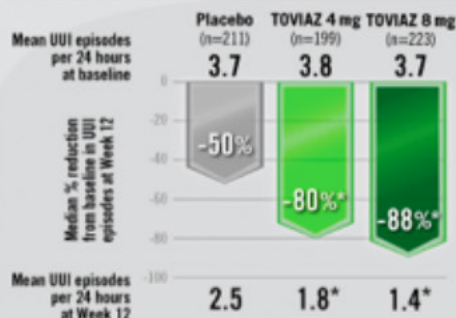




Powerful efficacy in reducing urge urinary incontinence

In a placebo-controlled study

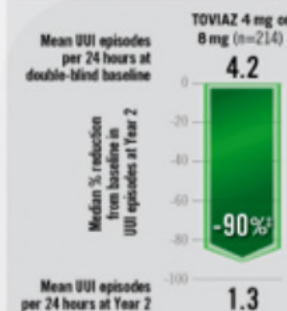
88% median reduction in urge urinary incontinence with TOVIAZ 8 mg at Week 12^{1,2}



*P<0.001 vs placebo.¹

For patients opting into the safety and tolerability open-label extension¹

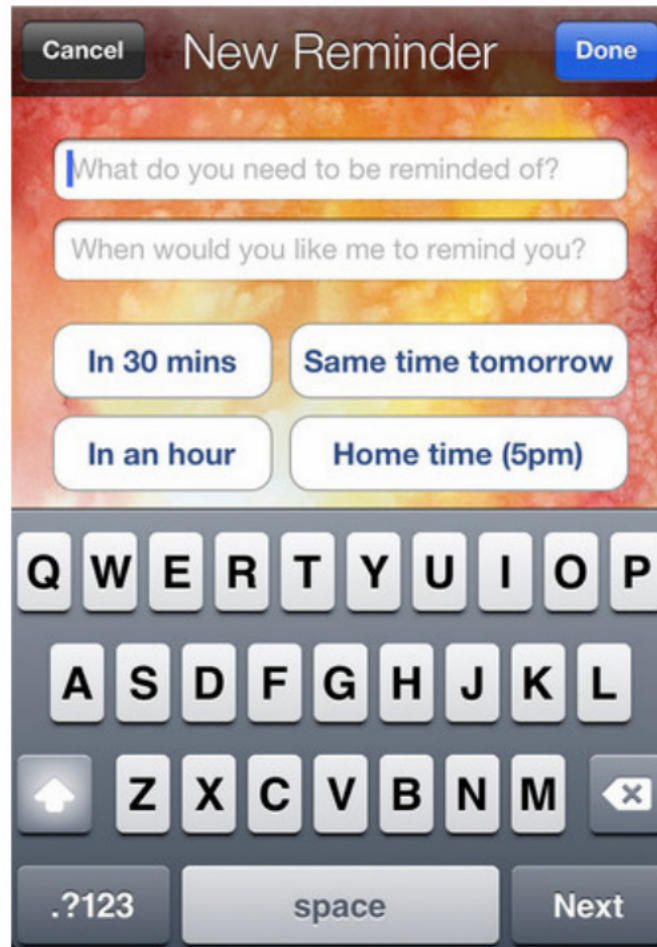
90% median reduction in urge urinary incontinence at Year 2³



¹Open-label extension began at end of the 12-week, placebo-controlled study.¹

³P<0.001 vs double-blind baseline.¹

Toviaz Mobile App



Toviaz Mobile App

« Kegelmater Home

Print Page

BLADDER DIARY

Day _____

Date: _____

S=Small M=Medium L=Large

TIME	FLUIDS		URINATION				ACCIDENTS		
	What kind?	How much?	How many times?	How much? (S,M,L)	Did you feel a strong urge to urinate?	What activity did this interrupt?	Did you have an accident?	How much did you Leak? (S,M,L)	What were you doing at the time?
Sample	Milk	Regular Glass	1	S	☒ Yes ☐ No	Watching TV	Yes ☒ No	—	Walking my dog
6-9 am					Yes No		Yes No		
9-12 noon					Yes No		Yes No		
12-3 pm					Yes No		Yes No		
3-6 pm					Yes No		Yes No		
6-9 pm					Yes No		Yes No		
9-12 mid					Yes No		Yes No		
12-3 am					Yes No		Yes No		
3-6 am					Yes No		Yes No		

Day _____

Date: _____

S=Small M=Medium L=Large



Conclusion

- Toviaz 8mg has proven superiority vs. Detrol LA 4mg in reducing urge urinary incontinence
- This campaign aims to show how Toviaz is the preferred treatment option for overactive bladder and allows patients to enjoy life's activities without being hindered by the need to go.

With Toviaz, Don't Let Overactive Bladder Stop You In Your Tracks...



Works Cited

"Aging Statistics." Administration on Aging. Department of Health and Human Services, 1 Sept. 2001. Web. 15 Apr. 2013. <http://www.aoa.gov/Aging_Statistics/>.

"Evaluating Prescription Drugs Used to Treat: Overactive Bladder Comparing Effectiveness, Safety, and Price." Health.org. Consumer Reports, n.d. Web. <http://www.consumerreports.org/health/resources/pdf/best-buy-drugs/Overactive_Bladder-FINAL.pdf>.

"Global Overactive Bladder (OAB) Therapeutics Market to Exceed \$4.0 Billion by 2017, According to a New Report by Global Industry Analysts, Inc." PRWeb. N.p., n.d. Web. 21 Apr. 2013. <http://www.prweb.com/releases/overactive_bladder/OAB_therapeutics/prweb8585241.htm>.

Leonhauser, Melissa. "Overactive Bladder Market: Managing the Future." PM360Online. IMS Health, Apr. 2012. Web. 15 Apr. 2013. <http://www.imshealth.com/ims/Global/Content/Corporate/Press%20Room/IMS%20in%20the%20News/Documents/Overactive_Bladder_Market1.pdf>.

"Overactive Bladder Treatment & Management." Medscape Reference. N.p., n.d. Web. 18 Apr. 2013. <<http://emedicine.medscape.com/article/459340-treatment>>.

Works Cited Continued

Pfizer For Professionals. Pfizer, n.d. Web. 21 Apr. 2013.

<<http://www.pfizerpro.com/hcp/toviaz/efficacy>>.

"Superiority." Pfizer for Professionals. Pfizer, n.d. Web. 21 Apr. 2013.

<<http://www.pfizerpro.com/hcp/toviaz/superiority>>.

"The OAB Therapeutics Market Is Forecast to Decline up to 2019." ASDReports.

N.p., n.d. Web. 2 Apr. 2013. <https://www.asdreports.com/news.asp?pr_id=255>.

"Therapeutic Class ReviewSM Urology: Overactive Bladder – Fesoterodine (Toviaz®)." ReGenceRx Pharmacy Benefit Management, Apr. 2009. Web.

<<http://www.regencerx.com/docs/physicianRx/urology-toviaz-04-2009.pdf>>.

"TOVIAZ 4 Mg Prolonged-release Tablets & TOVIAZ 8 Mg Prolonged-release Tablets." EMC. N.p., 19 Oct. 2012. Web. 10 Apr. 2013.

<http://www.medicines.org.uk/emc/medicine/20928/SPC/TOVIAZ+4+mg+prolonged-release+tablets+%26+TOVIAZ+8+mg+prolonged-release+tablets/#CLINICAL_PARTS>.