



Exemples d'énoncés de juste
équilibre et de destination
du lien dans Internet
(publicité destinée aux
professionnels de la santé)

Contenu du document d'orientation

But

L'ancien

Figure 1 : Annonce dans des revues

Figure 2 : Résumé des renseignements posologiques

Le nouveau

Figure 3 : Niveau ultime d'énoncé de juste équilibre sur Toviaz

Figure 4 : Destination du lien dans Internet

Figure 5 : Destination du lien dans Internet qui contient des références et des paramètres d'études

Utilisation du niveau moyen pour mener vers le niveau ultime d'énoncé de juste équilibre

Figure 6 : Exemple d'annonce dans des revues sur Toviaz

Figure 7 : Niveau ultime d'énoncé de juste équilibre placé ailleurs

Figure 8 : Niveau ultime d'énoncé de juste équilibre placé ailleurs avec des références et des paramètres d'études

Autres utilisations clés du niveau moyen d'énoncé de juste équilibre pour mener au niveau ultime d'énoncé de juste équilibre

Figure 9 : Taille de polices de caractères pour du contenu qui n'est pas situé sur le recto de l'annonce

Figure 10 : Règle coulissante

Figure 11 : Porte-échantillons

But

Le présent document est fondamentalement un recueil d'exemples. Il a pour but de cristalliser les principes des articles 4,4 et 7,3 du code du CCPP et les concepts expliqués dans les documents d'orientation du CCPP « Document d'orientation sur la création des trois niveaux de base d'énoncés de juste équilibre (publicité destinée aux professionnels de la santé) » et « Document d'orientation sur la sélection et le placement du niveau de base de l'énoncé de juste équilibre dans les SPP destinés aux professionnels de la santé ». Il est fortement recommandé de lire ces documents avant de lire celui-ci.

L'ancien

La Figure 1 présente l'annonce dans des revues sur Toviaz en 2012 tandis que la Figure 2 montre les renseignements posologiques auxquels cette annonce fait référence.

Figure 1 : Mise en page de l'annonce dans les revues sur Toviaz en 2012 (c.-à-d. avant les modifications au code) (rétrécie pour correspondre à la page)

Figure 3: Layout for a 2012 Toviaz journal ad (shrunk to fit page).

TODAY THERE'S P **Toviaz**™



A NEW OPTION FOR YOUR OAB† PATIENTS

Based on clinical studies, no apparent overall differences were observed in safety between older (patients ≥65 years) and younger patients (patients <65 years) on TOVIAZ. Therefore, dosage adjustment for geriatric patients may not be required. Adverse events that occurred at an incidence of ≥3% with TOVIAZ were dry mouth (18.8% 4 mg and 34.6% 8 mg), constipation (4.2% 4 mg and 6.0% 8 mg), urinary tract infection (3.2% 4 mg and 4.2% 8 mg), and dry eyes (1.4% 4 mg and 3.7% 8 mg). TOVIAZ is contraindicated in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, hypersensitivity to this drug, tolterodine L-tartrate tablets, tolterodine L-tartrate extended-release capsules, soya, peanuts, lactose, and any of the other ingredients in the formulation or any component of the container. Angioedema of the face, lips, tongue, and/or larynx has been reported with fesoterodine. In some cases angioedema occurred after the first dose. Angioedema associated with upper airway swelling may be life-threatening. If involvement of the tongue, hypopharynx, or larynx occurs, fesoterodine should be promptly discontinued and appropriate therapy and/or measures to ensure a patent airway should be promptly provided. TOVIAZ, like other antimuscarinic drugs, is associated with increased heart rate that correlates with increasing dose. Accordingly, as with other antimuscarinic drugs, caution should be used when administering TOVIAZ to patients who have a history of ischemic heart disease or tachyarrhythmias. In the placebo-controlled phase 3 studies, the mean increase in heart rate, compared to placebo, were approximately 3-4 beats/minute in the 4 mg/day group and 3-5 beats/minute in the 8 mg/day group. TOVIAZ is not recommended for use in patients with severe hepatic impairment (Child-Pugh C). For patients with severe renal impairment (CL_{CR} <30 mL/min) or patients treated with potent CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, miconazole, and clarithromycin), doses of TOVIAZ greater than 4 mg are not recommended.

For complete prescribing information, please refer to the Product Monograph. The Product Monograph is available upon request.

References: 1. Pfizer Canada Inc. TOVIAZ Product Monograph, February 2012. 2. Nitti VW et al. Efficacy, safety and tolerability of fesoterodine for overactive bladder syndrome. *J Urol* 2007;178:2483-2494. 3. Herschorn S et al. Comparison of fesoterodine and tolterodine extended release for the treatment of overactive bladder: A head-to-head placebo-controlled trial. *BJU Int* 2010;105:58-66. 4. Kaplan SA et al. Superior efficacy of fesoterodine over tolterodine extended release with rapid onset: A prospective, head-to-head placebo-controlled trial. *BJU Int* 2011;107:1432-1440.

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Are your OAB patients on the verge of experiencing an accident?

TOVIAZ (fesoterodine fumarate extended-release tablet) is indicated for the treatment of patients with OAB with symptoms of urinary frequency, urgency, or urge incontinence, or any combination of these symptoms.

Different by design^{1,‡}

- The conversion of TOVIAZ to its active metabolite, 5-hydroxymethyl tolterodine (5-HMT), is not dependent on cytochrome P450 liver enzymes

Demonstrated efficacy in treating OAB symptoms

- Up to 5X decrease in urgency episodes/24 hrs vs. placebo at Week 12[§]
- Median % change from baseline: -16.3% TOVIAZ 4 mg and -18.4% TOVIAZ 8 mg vs. -3.3% placebo ($p < 0.001$; baseline means were 12.5, 11.6, and 11.4, respectively)[‡]

Demonstrated superiority in treating UII* episodes/24 hrs with TOVIAZ 8 mg vs. tolterodine ER 4 mg in 2 head-to-head trials at Week 12^{§,††,‡‡}

- Winsorized mean changes from baseline:
 - Study 1: -1.5 placebo, -1.6 tolterodine ER, and -1.7 TOVIAZ ($p = 0.017$ TOVIAZ vs. tolterodine ER)
 - Study 2: -1.6 placebo, -1.7 tolterodine ER, and -2.0 TOVIAZ ($p = 0.0072$ TOVIAZ vs. tolterodine ER)

Demonstrated safety and tolerability profile¹

- Most common adverse events ≥5%: dry mouth (18.8% 4 mg and 34.6% 8 mg) and constipation (4.2% 4 mg and 6.0% 8 mg)
- Discontinuation rates due to dry mouth were 0.4% and 0.8% in patients receiving TOVIAZ 4 mg and 8 mg, respectively^{§§}

Flexible dosing¹

- Available in two different dosage strengths: 4 mg and 8 mg

† OAB=Overactive Bladder
‡ Comparative clinical significance has not been established
§ Randomized, double-blind, placebo-controlled, multicentre study of patients with OAB symptoms including urinary frequency and either urinary urgency or UII. Patients were randomized to receive placebo (n=274), TOVIAZ 4 mg (n=203), or TOVIAZ 8 mg (n=273) once-daily for 12 weeks. Number of patients evaluated for urgency episodes/24 hrs was 256, 267, and 267, respectively.
¶ UII=urge urinary incontinence
†† 12-week, double-blind, double-dummy, placebo-controlled, parallel-group, randomized clinical trial of patients with OAB (≥8 voids and ≥1 UII episodes/24 hrs in 3-day bladder diaries at baseline) randomized to placebo (n=334), maximum dose of tolterodine ER 4 mg (n=934), or maximum dose of TOVIAZ 4 mg for 1 week then 8 mg for 11 weeks; n=579. Number of patients evaluated for UII episodes/24 hrs was 307, 626, and 613, respectively. Baseline means for UII episodes/24 hrs were 2.6, 2.5, and 2.4, respectively.
‡‡ 12-week, double-blind, double-dummy, placebo-controlled, parallel-group, randomized clinical trial of patients with OAB (≥8 voids and ≥1 UII episodes/24 hrs in 3-day bladder diaries at baseline) randomized to placebo (n=478), maximum dose of tolterodine ER 4 mg (n=573), or maximum dose of TOVIAZ 4 mg for 1 week then 8 mg for 11 weeks; n=950. Number of patients evaluated for UII episodes/24 hrs was 448, 925, and 908, respectively. Baseline means for UII episodes/24 hrs were 2.4, 2.6, and 2.6, respectively.
§§ A total of 1954 patients participated in two 12-week, Phase 3 efficacy and safety studies. In these 2 studies combined, 554 patients received TOVIAZ 4 mg/day and 566 patients received TOVIAZ 8 mg/day.



Working together for a healthier world™

NEW

Toviaz™

fesoterodine fumarate
extended-release tablets 4 mg and 8 mg

f See prescribing summary on page

L'énoncé de juste équilibre se trouve dans le quadrant inférieur gauche. De plus, l'icône dans le quadrant inférieur à l'extrême droite dirige le lecteur vers la page 76 de la publication où se trouve le résumé des renseignements posologiques. La Figure 2 présente le résumé des renseignements posologiques qui s'étale sur 2 pages. C'est ce que le lecteur voit lorsqu'il arrive à la page 76.

Figure 2 : Résumé des renseignements posologiques de 2012 sur Toviaz (2 pages)



Prescribing Summary

Patient Selection Criteria

THERAPEUTIC CLASSIFICATION: Anticholinergic – Antispasmodic Agent

INDICATIONS AND CLINICAL USE: TOVIAZ™ (fesoterodine fumarate extended-release tablet) is indicated for the treatment of patients with overactive bladder with symptoms of urinary frequency, urgency, or urge incontinence, or any combination of these symptoms. **Geriatrics (>65 years of age):** Based on clinical studies, no apparent overall differences were observed in safety between older patients >65 years and younger patients (patients <65 years) on fesoterodine extended-release tablets. Therefore, dosage adjustment for geriatric patients may not be required (see SPECIAL POPULATIONS). **Pediatrics (<18 years of age):** The safety and efficacy of TOVIAZ in pediatric populations have not been established.

CONTRAINDICATIONS: TOVIAZ is contraindicated in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, hypersensitivity to this drug, tolterodine L-tartrate tablets, tolterodine L-tartrate extended-release capsules, soya, peanuts, lactose, any of the other ingredients in the formulation or any component of the container.

SPECIAL POPULATIONS: **Pregnant Women:** There are no adequate data from the use of fesoterodine in pregnant women. Reproductive toxicity studies with fesoterodine in animals show embryotoxicity at doses close to maternally toxic ones. The potential risk for humans is unknown. Therefore, fesoterodine should be used during pregnancy only if the potential benefit to the mother outweighs the potential risk to the fetus. Women of childbearing potential should be considered for treatment only if using adequate contraception. **Nursing Women:** It is not known whether fesoterodine is excreted into human milk; therefore, breastfeeding is not recommended during treatment with fesoterodine. **Pediatrics (<18 years of age):** The safety and efficacy of TOVIAZ in pediatric patients have not been established. **Geriatrics (>65 years of age):** No overall differences in safety or effectiveness were observed between patients younger than 65 years of age and those 65 years of age or older in the clinical studies. However, patients in these studies were highly selected and relatively healthy. Dose-adjustment may not be required for the elderly. The pharmacokinetics of fesoterodine are not significantly influenced by age (see ADVERSE REACTIONS – Geriatrics).

Safety Information

WARNINGS AND PRECAUTIONS: **Cardiovascular:** TOVIAZ, like other antimuscarinic drugs, is associated with increased heart rate that correlates with increasing dose. Accordingly, as with other antimuscarinic drugs, caution should be used when administering TOVIAZ to patients who have a history of ischemic heart disease or tachyarrhythmias. **Endocrine/Metabolism:** **CYP3A4:** Caution should be exercised when prescribing or up-titrating fesoterodine from 4 mg to 8 mg in patients in whom an increased exposure to the active metabolite is expected, such as with concomitant administration of CYP3A4 inhibitors. In the presence of a potent CYP3A4 inhibitor (e.g., ketoconazole, itraconazole, miconazole, and clarithromycin), doses of TOVIAZ greater than 4 mg are not recommended. In the presence of moderate CYP3A4 inhibitors (e.g., fluconazole), no dosing adjustments are recommended. While the effect of weak CYP3A4 inhibitors (e.g., cimetidine) was not examined in a clinical study, some pharmacokinetic interaction is expected, though less than what was observed with moderate CYP3A4 inhibitors (see ADMINISTRATION and Supplemental Product Information). **CYP2D6:** A subset of individuals are poor metabolizers for CYP2D6. Compared with CYP2D6 extensive metabolizers not taking ketoconazole (a potent CYP3A4 inhibitor), **Urinary Retention:** Increases in the exposure to the active metabolite of fesoterodine were observed in subjects who were CYP2D6 poor metabolizers taking ketoconazole (see Supplemental Product Information). **Gastrointestinal:** Patients at Risk of Gastric Retention: TOVIAZ, like other antimuscarinic drugs, should be administered with caution to patients with decreased gastrointestinal motility, including patients with severe constipation and to patients with gastrointestinal obstruction disorders (e.g., pyloric stenosis) because of the risk of gastric retention (see CONTRAINDICATIONS). **Genitourinary:** Patients at Risk of Urinary Retention: TOVIAZ, like other antimuscarinic drugs, should be administered with caution to patients with clinically significant bladder outlet obstruction because of the risk of urinary retention (see CONTRAINDICATIONS and Supplemental Product Information). **Hepatic/Biliary/Pancreatic:** TOVIAZ should be administered with caution to patients with impaired hepatic function. In patients with mild to moderate hepatic impairment, no dosage adjustment is required. Fesoterodine is not recommended for use in patients with severe hepatic impairment (see ADMINISTRATION). **Immune:** **Angioedema:** Angioedema of the face, lips, tongue, and/or larynx has been reported with fesoterodine. In some cases angioedema occurred after the first dose. Angioedema associated with upper airway swelling may be life-threatening. If involvement of the tongue, hypopharynx, or larynx occurs, fesoterodine should be promptly discontinued and appropriate therapy and/or measures to ensure a patent airway should be promptly provided. **Lactose:** TOVIAZ extended-release tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the

Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicinal product. **Neurologic:** TOVIAZ, like other antimuscarinic drugs, should be administered with caution to patients with myasthenia gravis. **Ophthalmologic:** Controlled Narrow-Angle Glaucoma: TOVIAZ, like other antimuscarinic drugs, should be used with caution in patients being treated for narrow-angle glaucoma (see CONTRAINDICATIONS). **Renal:** TOVIAZ should be administered with caution to patients with impaired renal function. In patients with mild-to-moderate renal impairment, no dosage adjustment is required. Doses of fesoterodine greater than 4 mg are not recommended in patients with severe renal impairment (CL_{CR}<30 mL/min) (see ADMINISTRATION).

ADVERSE REACTION (see full listing): **Adverse Drug Reaction Overview:** Due to the pharmacological properties of fesoterodine, treatment may cause mild-to-moderate antimuscarinic effects like dry mouth, constipation, dry eyes, and dyspepsia. **Clinical Trial Adverse Drug Reactions:** The safety of TOVIAZ was primarily evaluated in Phase 2 and 3 controlled trials in a total of 2858 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. A total of 1964 patients participated in two 12-week, Phase 3 efficacy and safety studies and subsequent open-label extension studies. In these 2 studies combined, 554 patients received TOVIAZ 4 mg/day and 566 patients received TOVIAZ 8 mg/day. In Phase 2 and 3 placebo-controlled trials combined, the incidence 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. The most commonly reported adverse event in patients treated with TOVIAZ was dry mouth. The incidence of dry mouth was higher in those taking 8 mg/day (35%) and in those taking 4 mg/day (19%), as compared to placebo (7%). Dry mouth led to discontinuation in 0.4%, 0.4%, and 0.8% of patients receiving placebo, TOVIAZ 4 mg, and TOVIAZ 8 mg, respectively. For those patients who reported dry mouth, most had their first occurrence of the event within the first month of treatment. The second most commonly reported adverse event was constipation. The incidence of constipation was 2% in those taking placebo, 4% in those taking TOVIAZ 4 mg/day, and 6% in those taking TOVIAZ 8 mg. Patients also received TOVIAZ for up to three years in open-label extension phases of one Phase 2 and two Phase 3 controlled trials. In all open-label trials combined, 857, 701, 529, and 105 patients received TOVIAZ for at least 6 months, 1 year, 2 years, and 3 years, respectively. The adverse events observed during long-term, open-label studies were similar to those observed in the 12-week, placebo-controlled studies, and included dry mouth, constipation, dry eyes, dyspepsia, and abdominal pain. Similar to the controlled studies, most adverse events of dry mouth and constipation were mild to moderate in intensity. Serious adverse events, judged to be at least possibly related to study medication by the investigator, and reported more than once during the open-label treatment period of up to 3 years included urinary retention (3 cases), diverticulitis (3 cases), constipation (2 cases), irritable bowel syndrome (2 cases), and electrocardiogram QT corrected interval prolongation (2 cases). The safety of TOVIAZ was further established in two additional 12-week, active- and placebo-controlled, double-blind, randomized studies comparing TOVIAZ with tolterodine ER 4 mg and placebo. In these studies combined, 1527 patients received TOVIAZ 8 mg, 1552 patients received tolterodine ER 4 mg, and 755 patients received placebo. The most common treatment-emergent adverse events (dry mouth, constipation, and headache) reported with TOVIAZ during these 2 studies were similar to those observed in the 12-week, placebo-controlled studies. In clinical trials comparing fesoterodine to placebo, cases of markedly elevated liver enzymes (ALT increased, GGT increased) were reported at a frequency no different than placebo. The relation to fesoterodine treatment is unclear. TOVIAZ was associated with an increase in heart rate that correlated with increasing dose, a well-characterized effect described for antimuscarinic drugs. In the placebo-controlled phase 3 studies in patients with overactive bladder, the mean increases in heart rate compared to placebo were approximately 3-4 beats/minute in the 4 mg/day group and 3-5 beats/minute in the 8 mg/day group. **Geriatrics (>65 years of age):** Of 1567 patients who received TOVIAZ 4 mg/day or 8 mg/day in the Phase 2 and 3, placebo-controlled, efficacy and safety studies, 515 (33%) were 65 years of age or older, and 140 (9%) were 75 years of age or older. No overall differences in safety or efficacy were observed between patients younger than 65 years of age and those 65 years of age or older in these studies; however, the incidence of antimuscarinic adverse events, including dry mouth, constipation, dyspepsia, increase in residual urine, dizziness (at 8 mg only) and urinary tract infection, was higher in patients 75 years of age and older as compared to younger patients. **Post-Market Adverse Drug Reactions:** The following events have been reported in association with fesoterodine use in worldwide post-marketing experience: **Eye disorders:** Blurred vision; **Cardiac disorders:** Palpitations; **Skin and subcutaneous tissue disorders:** Angioedema including angioedema with airway obstruction, face edema, hypersensitivity reactions; **Renal and urinary disorders:** Urinary retention. Because these spontaneously reported events are from the worldwide post-marketing experience, the frequency of the events and the role of fesoterodine in their causation cannot be reliably determined.

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/mdeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program, Health Canada
Postel Locator 0701C, Ottawa, ON K1A 0N6



Administration

Dosing Considerations: Dosing of TOVIAZ (fesoterodine fumarate) may be affected by the following: individual response and tolerability, impaired hepatic function and renal impairment, potent CYP3A4 inhibitors (see **WARNINGS AND PRECAUTIONS** and **ADMINISTRATION, Recommended Dose and Dosage Adjustment**). **Recommended Dose and Dosage Adjustment:** The recommended starting dose of TOVIAZ is 4 mg once daily. Based upon individual response and tolerability, the dose may be increased to 8 mg once daily. The daily dose of TOVIAZ should not exceed 4 mg in the following populations: patients with severe renal impairment ($CL_{CR} < 30$ mL/min) and patients taking potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, miconazole, and clarithromycin. TOVIAZ is not recommended for use in patients with severe hepatic impairment (Child-Pugh C). Dosage adjustment may not be necessary for elderly patients (>65 years of age) (see **SPECIAL POPULATIONS**). **Administration:** TOVIAZ tablets should be taken with liquid and swallowed whole. TOVIAZ can be administered with or without food, and should not be chewed, divided, or crushed. TOVIAZ may be taken during the day or at night.

Supplemental Product Information

ADVERSE REACTIONS: Clinical Trial Adverse Drug Reactions: Because clinical trials are conducted under very specific conditions, the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice. The following table lists adverse drug reaction information from clinical trials that could be affecting drug-related adverse events and by approximate rate. The following table lists adverse events, regardless of causality, that were reported in the clinical Phase 3, randomized, placebo-controlled trial of fesoterodine fumarate compared to 15-week of patients treated with TOVIAZ 4 mg once daily for up to 12 weeks.

Table 1: Adverse events with an incidence exceeding the placebo rate and reported by $>1\%$ of patients in two double-blind, placebo-controlled Phase 3 trials of 12 weeks treatment duration

System organ class/Preferred term	Placebo n=554 %	TOVIAZ 4 mg/day n=554 %	TOVIAZ 8 mg/day n=556 %
Gastrointestinal disorders			
Dry mouth	7.9	18.8	34.6
Constipation	2.0	4.2	6.0
Dyspepsia	0.5	1.6	2.3
Nausea	1.3	0.7	1.9
Abdominal pain upper	0.5	1.1	0.5
Infections			
Urinary tract infection	3.1	3.2	4.2
Upper respiratory tract infection	2.2	2.5	1.8
Eye disorders			
Dry eyes	0	1.4	3.7
Renal and urinary disorders			
Urinary retention	0.2	1.1	1.4
Respiratory disorders			
Cough	0.5	1.6	0.9
Dry throat	0.4	0.9	2.3
General disorders			
Edema peripheral	0.7	0.7	1.2
Musculoskeletal disorders			
Back pain	0.4	2.0	0.9
Psychiatric disorders			
Insomnia	0.5	1.3	0.4
Investigations			
ALT increased	0.9	0.5	1.2
Skin disorders			
Rash	0.4	0.4	1.2
	0.5	0.7	1.1

ALT = alanine aminotransferase; CYP = cytochrome

DRUG-DRUG INTERACTIONS: In a pharmacokinetic (PK) study, co-administration of TOVIAZ with other anticholinergic products with anticholinergic properties may result in more pronounced dry mouth and/or urinary effects. TOVIAZ is a weak inhibitor of cytochrome P450 (CYP) 2D6, 2C19, 3A4, 2C9, 2C8, 2C18, 2C19, 2C20, 2C22, 2C24, 2C26, 2C27, 2C28, 2C29, 2C30, 2C35, 2C37, 2C39, 2C42, 2C43, 2C44, 2C45, 2C46, 2C47, 2C48, 2C49, 2C50, 2C51, 2C52, 2C53, 2C54, 2C55, 2C56, 2C57, 2C58, 2C59, 2C60, 2C61, 2C62, 2C63, 2C64, 2C65, 2C66, 2C67, 2C68, 2C69, 2C70, 2C71, 2C72, 2C73, 2C74, 2C75, 2C76, 2C77, 2C78, 2C79, 2C80, 2C81, 2C82, 2C83, 2C84, 2C85, 2C86, 2C87, 2C88, 2C89, 2C90, 2C91, 2C92, 2C93, 2C94, 2C95, 2C96, 2C97, 2C98, 2C99, 2C100, 2C101, 2C102, 2C103, 2C104, 2C105, 2C106, 2C107, 2C108, 2C109, 2C110, 2C111, 2C112, 2C113, 2C114, 2C115, 2C116, 2C117, 2C118, 2C119, 2C120, 2C121, 2C122, 2C123, 2C124, 2C125, 2C126, 2C127, 2C128, 2C129, 2C130, 2C131, 2C132, 2C133, 2C134, 2C135, 2C136, 2C137, 2C138, 2C139, 2C140, 2C141, 2C142, 2C143, 2C144, 2C145, 2C146, 2C147, 2C148, 2C149, 2C150, 2C151, 2C152, 2C153, 2C154, 2C155, 2C156, 2C157, 2C158, 2C159, 2C160, 2C161, 2C162, 2C163, 2C164, 2C165, 2C166, 2C167, 2C168, 2C169, 2C170, 2C171, 2C172, 2C173, 2C174, 2C175, 2C176, 2C177, 2C178, 2C179, 2C180, 2C181, 2C182, 2C183, 2C184, 2C185, 2C186, 2C187, 2C188, 2C189, 2C190, 2C191, 2C192, 2C193, 2C194, 2C195, 2C196, 2C197, 2C198, 2C199, 2C200, 2C201, 2C202, 2C203, 2C204, 2C205, 2C206, 2C207, 2C208, 2C209, 2C210, 2C211, 2C212, 2C213, 2C214, 2C215, 2C216, 2C217, 2C218, 2C219, 2C220, 2C221, 2C222, 2C223, 2C224, 2C225, 2C226, 2C227, 2C228, 2C229, 2C230, 2C231, 2C232, 2C233, 2C234, 2C235, 2C236, 2C237, 2C238, 2C239, 2C240, 2C241, 2C242, 2C243, 2C244, 2C245, 2C246, 2C247, 2C248, 2C249, 2C250, 2C251, 2C252, 2C253, 2C254, 2C255, 2C256, 2C257, 2C258, 2C259, 2C260, 2C261, 2C262, 2C263, 2C264, 2C265, 2C266, 2C267, 2C268, 2C269, 2C270, 2C271, 2C272, 2C273, 2C274, 2C275, 2C276, 2C277, 2C278, 2C279, 2C280, 2C281, 2C282, 2C283, 2C284, 2C285, 2C286, 2C287, 2C288, 2C289, 2C290, 2C291, 2C292, 2C293, 2C294, 2C295, 2C296, 2C297, 2C298, 2C299, 2C300, 2C301, 2C302, 2C303, 2C304, 2C305, 2C306, 2C307, 2C308, 2C309, 2C310, 2C311, 2C312, 2C313, 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2C457, 2C458, 2C459, 2C460, 2C461, 2C462, 2C463, 2C464, 2C465, 2C466, 2C467, 2C468, 2C469, 2C470, 2C471, 2C472, 2C473, 2C474, 2C475, 2C476, 2C477, 2C478, 2C479, 2C480, 2C481, 2C482, 2C483, 2C484, 2C485, 2C486, 2C487, 2C488, 2C489, 2C490, 2C491, 2C492, 2C493, 2C494, 2C495, 2C496, 2C497, 2C498, 2C499, 2C500, 2C501, 2C502, 2C503, 2C504, 2C505, 2C506, 2C507, 2C508, 2C509, 2C510, 2C511, 2C512, 2C513, 2C514, 2C515, 2C516, 2C517, 2C518, 2C519, 2C520, 2C521, 2C522, 2C523, 2C524, 2C525, 2C526, 2C527, 2C528, 2C529, 2C530, 2C531, 2C532, 2C533, 2C534, 2C535, 2C536, 2C537, 2C538, 2C539, 2C540, 2C541, 2C542, 2C543, 2C544, 2C545, 2C546, 2C547, 2C548, 2C549, 2C550, 2C551, 2C552, 2C553, 2C554, 2C555, 2C556, 2C557, 2C558, 2C559, 2C560, 2C561, 2C562, 2C563, 2C564, 2C565, 2C566, 2C567, 2C568, 2C569, 2C570, 2C571, 2C572, 2C573, 2C574, 2C575, 2C576, 2C577, 2C578, 2C579, 2C580, 2C581, 2C582, 2C583, 2C584, 2C585, 2C586, 2C587, 2C588, 2C589, 2C590, 2C591, 2C592, 2C593, 2C594, 2C595, 2C596, 2C597, 2C598, 2C599, 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2C743, 2C744, 2C745, 2C746, 2C747, 2C748, 2C749, 2C750, 2C751, 2C752, 2C753, 2C754, 2C755, 2C756, 2C757, 2C758, 2C759, 2C760, 2C761, 2C762, 2C763, 2C764, 2C765, 2C766, 2C767, 2C768, 2C769, 2C770, 2C771, 2C772, 2C773, 2C774, 2C775, 2C776, 2C777, 2C778, 2C779, 2C780, 2C781, 2C782, 2C783, 2C784, 2C785, 2C786, 2C787, 2C788, 2C789, 2C790, 2C791, 2C792, 2C793, 2C794, 2C795, 2C796, 2C797, 2C798, 2C799, 2C800, 2C801, 2C802, 2C803, 2C804, 2C805, 2C806, 2C807, 2C808, 2C809, 2C810, 2C811, 2C812, 2C813, 2C814, 2C815, 2C816, 2C817, 2C818, 2C819, 2C820, 2C821, 2C822, 2C823, 2C824, 2C825, 2C826, 2C827, 2C828, 2C829, 2C830, 2C831, 2C832, 2C833, 2C834, 2C835, 2C836, 2C837, 2C838, 2C839, 2C840, 2C841, 2C842, 2C843, 2C844, 2C845, 2C846, 2C847, 2C848, 2C849, 2C850, 2C851, 2C852, 2C853, 2C854, 2C855, 2C856, 2C857, 2C858, 2C859, 2C860, 2C861, 2C862, 2C863, 2C864, 2C865, 2C866, 2C867, 2C868, 2C869, 2C870, 2C871, 2C872, 2C873, 2C874, 2C875, 2C876, 2C877, 2C878, 2C879, 2C880, 2C881, 2C882, 2C883, 2C884, 2C885, 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Figure 3 : Niveau de base ultime d'énoncé de juste équilibre sur Toviaz

Cette figure présente un exemple de modifications apportées à une annonce déjà existante dans une revue. Ces modifications n'ont pas été approuvées par Pfizer et sont uniquement présentées à des fins de formation.

This is an example of modifications to an existing journal ad. These modifications have not been approved by Pfizer and are being shown for training purposes only.

TODAY THERE'S Toviaz™



A NEW OPTION
FOR YOUR
OAB†
PATIENTS

Clinical use:
Safety and efficacy in pediatric populations have not been established.

Contraindications:

- Urinary retention
- Gastric retention
- Uncontrolled narrow-angle glaucoma
- Hypersensitivity to tolterodine L tartrate, soya, peanuts, lactose

Relevant warnings and precautions

- Increase in heart rate
- Interaction with potent CYP3A4 inhibitors
- Patients at risk of gastric retention
- Patients at risk of urinary retention
- Patients with impaired hepatic function
- Angioedema

- Patients with myasthenia gravis
- Patients with controlled narrow-angle glaucoma
- Patients with impaired renal function
- Use of contraception in women of childbearing potential

For more information:
Please consult the Product Monograph at www.toviaz.ca/PM1583 for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece.
The Product Monograph is also available by calling us at 1-800-XXX-XXXX

Are your OAB patients on the verge of experiencing an accident?

TOVIAZ (fesoterodine fumarate extended-release tablet) is indicated for the treatment of patients with OAB 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-hydroxymethyl tolterodine (5-HMT), is not dependent on cytochrome P450 liver enzymes

Demonstrated efficacy in treating OAB symptoms

- Up to 5X decrease in urgency episodes/24 hrs vs. placebo at Week 12[§]
– Median % change from baseline: -16.3% TOVIAZ 4 mg and -18.4% TOVIAZ 8 mg vs. -3.3% placebo ($p < 0.001$; baseline means were 12.5, 11.6, and 11.4, respectively)[§]

Demonstrated superiority in treating UII[¶] episodes/24 hrs with TOVIAZ 8 mg vs. tolterodine ER 4 mg in 2 head-to-head trials at Week 12^{‡,¶,††}

- Winsorized mean changes from baseline:
– Study 1: -1.5 placebo, -1.6 tolterodine ER, and -1.7 TOVIAZ ($p = 0.017$ TOVIAZ vs. tolterodine ER)
– Study 2: -1.6 placebo, -1.7 tolterodine ER, and -2.0 TOVIAZ ($p = 0.0072$ TOVIAZ vs. tolterodine ER)

Demonstrated safety and tolerability profile[‡]

- Most common adverse events $\geq 5\%$: dry mouth (18.8% 4 mg and 34.6% 8 mg) and constipation (4.2% 4 mg and 6.0% 8 mg)
- Discontinuation rates due to dry mouth were 0.4% and 0.8% in patients receiving TOVIAZ 4 mg and 8 mg, respectively^{§§}

Flexible dosing[‡]

- Available in two different dosage strengths: 4 mg and 8 mg

† OAB=Overactive Bladder
‡ Comparative clinical significance has not been established.
§ Randomized, double-blind, placebo-controlled, multicentre study of patients with OAB symptoms including urinary frequency and either urinary urgency or UII. Patients were randomized to receive placebo (n=24), TOVIAZ 4 mg (n=28), or TOVIAZ 8 mg (n=29) once-daily for 12 weeks. Number of patients evaluated for urgency episodes/24 hrs was 266, 267, and 267, respectively.
¶ UII=urge urinary incontinence
†† 12-week, double-blind, double-dummy, placebo-controlled, parallel-group, randomized clinical trial of patients with OAB (≥ 8 voids and ≥ 1 UII episodes/24 hrs in 3-day bladder diaries at baseline) randomized to placebo (n=234), maximum dose of tolterodine ER 4 mg (n=504), or maximum dose of TOVIAZ (4 mg for 1 week then 8 mg for 11 weeks; n=573). Number of patients evaluated for UII episodes/24 hrs was 307, 626, and 619, respectively. Baseline means for UII episodes/24 hrs were 2.6, 2.5, and 2.4, respectively.
‡‡ 12-week, double-blind, double-dummy, placebo-controlled, parallel-group, randomized clinical trial of patients with OAB (≥ 8 voids and ≥ 1 UII episodes/24 hrs in 3-day bladder diaries at baseline) randomized to placebo (n=478), maximum dose of tolterodine ER 4 mg (n=573), or maximum dose of TOVIAZ (4 mg for 1 week then 8 mg for 11 weeks; n=568). Number of patients evaluated for UII episodes/24 hrs was 448, 926, and 588, respectively. Baseline means for UII episodes/24 hrs were 2.4, 2.6, and 2.6, respectively.
§§ A total of 1964 patients participated in two 12-week, Phase 3 efficacy and safety studies. In these 2 studies combined, 534 patients received TOVIAZ 4 mg/day and 566 patients received TOVIAZ 8 mg/day.



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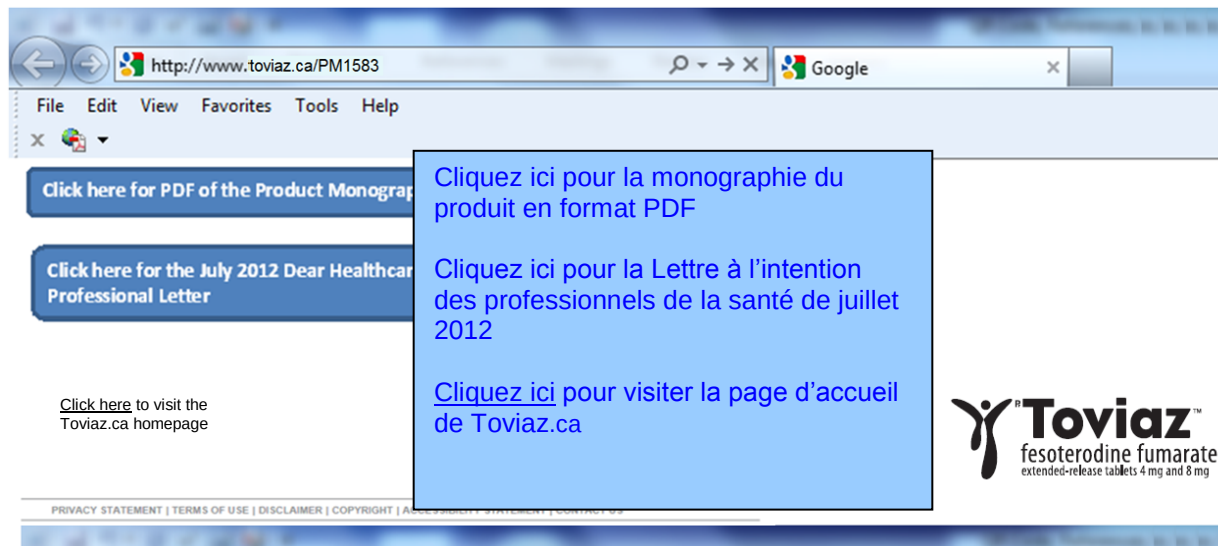
NEW

Toviaz™

fesoterodine fumarate
extended-release tablets 4 mg and 8 mg

La page Web à l'adresse URL www.toviaz.ca/PM1583 qui est montrée dans l'énoncé de juste équilibre de la Figure 3 est une page hypothétique du site protégé www.toviaz.ca destiné aux professionnels de la santé. La Figure 4 présente un exemple de ce à quoi pourrait ressembler cette page Web hypothétique (uniquement à des fins de formation, cette page Web n'existe pas et n'a pas été approuvée par Pfizer). Vous remarquerez que Toviaz ne comporte pas de Lettre à l'intention des professionnels de la santé de juillet 2012. L'icône correspondante a été ajoutée uniquement à des fins de démonstration.

Figure 4 : Destination du lien Web hypothétique sur Toviaz



Conformément à l'article 7.3 du code du CCPP, cette page doit être accessible sans avoir à taper un mot de passe. Cela est possible étant donné que le SPP qui renferme l'adresse URL est distribué ou rendu visualisable d'une façon contrôlée (c.-à-d. ciblée pour les professionnels de la santé). Par conséquent, l'adresse URL elle-même sert de clé d'entrée dans le site Web sur Toviaz. C'est pour cette raison que vous observerez que l'adresse URL n'est pas simplement www.toviaz.ca. La révision de cette page Web par le CCPP n'est pas nécessaire à condition que le contenu soit limité au contenu détaillé dans l'article 7.3.2b du code du CCPP. Les références et les paramètres d'études sont révisés dans le contexte du SPP correspondant.

La liste des références et les paramètres d'études peuvent apparaître dans le SPP comme le présente la Figure 3. Toutefois, ils auraient pu avoir été déplacés vers la destination du lien dans Internet comme le montre la Figure 5. L'invitation à cliquer vers l'AMM (et la Lettre à l'intention des professionnels de la santé le cas échéant) doit être **très** visible sur la destination du lien dans Internet (p. ex., au premier plan sur la page et en gros caractères).

Veuillez noter que les paramètres d'études et la liste des références peuvent apparaître soit sur le devant de la destination du lien Internet (comme à la Figure 5) ou peuvent être relégués à un clic publicitaire.

Figure 5 : Destination du lien Web hypothétique sur Toviaz (avec les références et les paramètres d'études)

Click here for PDF of the Product Monograph

Click here for the July 2012 Dear Healthcare Professional Letter

Reference List:

1. Pfizer Canada Inc. TOVIAZ Product Monograph. February 2012.
^{§§}A total of 1964 patients participated in two 12-week studies. 554 patients received TOVIAZ 4 mg/day and 566 patients received placebo.
2. Nitti VW *et al.* Efficacy, safety and tolerability of fesoterodine for overactive bladder. *Int J Urol* 2010;17:105-11.
3. Herschorn S *et al.* Comparison of fesoterodine and tolterodine in a head-to-head placebo-controlled trial. *BJU Int* 2010;105:58-66.
^{††}12-week, double-blind, double-dummy, placebo-controlled, parallel-group, randomized clinical trial of patients with OAB (>8 voids and >1 UUI episodes/24 hrs in 3-day bladder diaries at baseline) randomized to placebo (n=334); maximum dose of tolterodine ER 4 mg (n=684); or maximum dose of TOVIAZ (4 mg for 1 week then 8 mg for 11 weeks; n=679). Number of patients evaluated for UUI episodes/24 hrs was 307, 626, and 619, respectively. Baseline means for UUI episodes/24 hrs were 2.6, 2.5, and 2.4, respectively.
4. Kaplan SA *et al.* Superior efficacy of fesoterodine over tolterodine extended release with rapid onset: A prospective, head-to-head placebo-controlled trial. *BJU Int* 2011;107:1432-1440.
^{††}12-week, double-blind, double-dummy, placebo-controlled, parallel-group, randomized clinical trial of patients with OAB (>8 voids and >1 UUI episodes/24 hrs in 3-day bladder diaries at baseline) randomized to placebo (n=478); maximum dose of tolterodine ER 4 mg (n=973); or maximum dose of TOVIAZ (4 mg for 1 week then 8 mg for 11 weeks; n=960). Number of patients evaluated for UUI episodes/24 hrs was 448, 926, and 908, respectively. Baseline means for UUI episodes/24 hrs were 2.4, 2.6, and 2.6, respectively.

Toviaz
fesoterodine fumarate
extended-release tablets 4 mg and 8 mg

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Il est important de remarquer que les paramètres d'études sont les seules notes de bas de page qu'il est possible de reléguer à la destination du lien Internet. Par exemple, pour être conformes à l'article 2.1 du code du CCPP, les avertissements et les définitions doivent rester sur le recto de l'annonce (sur la même surface que les allégations auxquelles ils se rapportent).

Au lieu du site Web sur Toviaz, le fabricant aurait pu utiliser une adresse URL qui mène à la liste des monographies des produits dans le site Web de l'entreprise ou à la page de recherche de la Base de données sur les produits pharmaceutiques de Santé Canada. Ce choix imposerait certaines limites quant aux options du fabricant relativement à la liste de références et aux paramètres d'études.

Utilisation du niveau moyen pour mener au niveau ultime d'énoncé de juste équilibre

Le SPP présenté à la Figure 3 comporte le niveau ultime d'énoncé de juste équilibre étant donné qu'il contient des allégations thérapeutiques. Cependant, le fabricant pourrait plutôt choisir d'utiliser le niveau moyen d'énoncé de juste équilibre sur le recto du SPP puis d'orienter le lecteur vers une surface d'accès facile (c.-à-d. même média) et qui incite à une lecture facile. Dans la Figure 6, nous avons modifié le SPP de la Figure 3 pour illustrer cette option.

Figure 6 : Niveau moyen utilisé pour orienter le lecteur vers un niveau ultime d'énoncé de juste équilibre
 Cette option est traitée dans le document du CCPP « Document d'orientation sur la sélection et le placement du niveau de base de l'énoncé de juste équilibre contenu dans les SPP destinés aux professionnels de la santé »

An option discussed in the PAAB document "Guidance on base fair balance level selection and placement in healthcare professional APS"



TODAY THERE'S Toviaz™

A NEW OPTION FOR YOUR OAB† PATIENTS

Refer to the page in the bottom-right icon for additional safety information and for a web link to the product monograph discussing:

- Contraindications in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, hypersensitivity to tolterodine L tartrate, soya, peanuts, lactose
- Relevant warnings and precautions regarding increase in heart rate, interaction with potent CYP3A4 inhibitors, patients at risk of gastric retention, patients at risk of urinary retention, patients with impaired hepatic function, angioedema, patients with myasthenia gravis, patients with controlled narrow-angle glaucoma, patients with impaired renal function, and use of contraception in women of childbearing potential.
- Conditions of clinical use, adverse reactions, drug interactions, and dosing instructions

In addition, the web link contains the reference list and study parameters relating to this advertisement.

Member



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 TOVIAZ TM C.P. Pharmaceuticals International C.V., owner/
 Pfizer Canada Inc., Licensee
 © 2012 Pfizer Canada Inc., Kirkland, Quebec H9J 2M5

NEW
 **Toviaz™**
 fesoterodine fumarate
 extended-release tablets 4 mg and 8 mg

† OAB=Overactive Bladder
 ‡ Comparative clinical significance has not been established.
 ¶ UUI=urge urinary incontinence

**Are your OAB patients
on the verge of experiencing
an accident?**

TOVIAZ (fesoterodine fumarate extended-release tablet) is indicated for the treatment of patients with OAB with symptoms of urinary frequency, urgency, or urge incontinence, or any combination of these symptoms.

Different by design^{1‡}

- The conversion of TOVIAZ to its active metabolite, 5-hydroxymethyl tolterodine (5-HMT), is not dependent on cytochrome P450 liver enzymes

Demonstrated efficacy in treating OAB symptoms

- Up to 5X decrease in urgency episodes/24 hrs vs. placebo at Week 12^{2¶}
 - Median % change from baseline: -16.3% TOVIAZ 4 mg and -18.4% TOVIAZ 8 mg vs. -3.3% placebo ($p < 0.001$; baseline means were 12.5, 11.6, and 11.4, respectively)²

Demonstrated superiority in treating UUI[¶] episodes/24 hrs with TOVIAZ 8 mg vs. tolterodine ER 4 mg in 2 head-to-head trials at Week 12^{3,4††‡‡}

- Winsorized mean changes from baseline:
 - Study 1: -1.5 placebo, -1.6 tolterodine ER, and -1.7 TOVIAZ ($p = 0.017$ TOVIAZ vs. tolterodine ER)
 - Study 2: -1.6 placebo, -1.7 tolterodine ER, and -2.0 TOVIAZ ($p = 0.0072$ TOVIAZ vs. tolterodine ER)

Demonstrated safety and tolerability profile¹

- Most common adverse events $\geq 5\%$: dry mouth (18.8% 4 mg and 34.6% 8 mg) and constipation (4.2% 4 mg and 6.0% 8 mg)
- Discontinuation rates due to dry mouth were 0.4% and 0.8% in patients receiving TOVIAZ 4 mg and 8 mg, respectively⁴¹

Flexible dosing¹

- Available in two different dosage strengths: 4 mg and 8 mg

See Page XX for additional safety information

Lorsque le lecteur arrive à la page XX, il voit la Figure 7. Dans le cas présent, www.toviaz.ca/PM1583 correspond à la figure 5.

Étant donné que Toviaz ne comporte pas de mises en garde et précautions mises en évidence (c.-à-d. en caractères gras/encadrées) ni une longue liste de problèmes liés à l'usage clinique dans la section « Indications et usage clinique » de la monographie du produit, les avantages de l'utilisation d'un niveau moyen d'énoncé de juste équilibre à l'intérieur du message publicitaire pour orienter les professionnels de la santé vers un niveau ultime à un autre endroit, ne sont pas aussi prononcés qu'ils le seraient pour d'autres produits.

Figure 7 : Niveau ultime d'énoncé de juste équilibre placé à un autre endroit

	
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. Safety and efficacy in pediatric populations have not been established.	• patient at risk of urinary retention • patients with impaired hepatic function • angioedema • patients with myasthenia gravis • patients with controlled narrow-angle glaucoma • patients with impaired renal function • Use of contraception in women of childbearing potential
Contraindications: • Urinary retention • Gastric retention • Uncontrolled narrow-angle glaucoma • Hypersensitivity to tolterodine L-tartrate, soya, peanuts, lactose	For more information: Please consult the product monograph at www.toviaz.ca/PM1583 for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece.
Relevant warnings and precautions • increased in heart rate • interaction with potent CYP3A4 inhibitors • patient at risk of gastric retention	The product monograph is also available by calling us at 1-800-XXX-XXXX.

Cela nous amène à un autre emplacement possible pour les références et les paramètres d'études. Dans la Figure 8, nous avons ajouté les références et paramètres d'études à la surface qui contient le niveau ultime d'énoncé de juste équilibre (plutôt que de les conserver dans l'annonce ou de les déplacer vers la destination du lien Internet). Dans le cas présent, www.toviaz.ca/PM1583 correspond à la Figure 4.

La Figure 9 présente les tailles minimales de polices de caractères pour du contenu qui n'apparaît pas sur le recto de l'annonce. Ces exigences minimales sont en vigueur quoi qu'il en soit, que le contenu apparaisse dans la destination du lien Internet ou à un autre endroit comme une autre page à l'intérieur de la publication. Il n'y a pas de tailles minimales de polices de caractères pour les énoncés de juste équilibre qui se trouvent sur le recto de l'annonce (puisque la taille de police de caractères de l'énoncé de juste équilibre sur le recto de l'annonce doit être comparable à la taille de police de caractères utilisée pour le texte sur les avantages du produit).

Figure 8 : Niveau ultime d'énoncé de juste équilibre placé à un autre endroit, avec les références et les paramètres d'études



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.

Safety and efficacy in pediatric populations have not been established.

Contraindications:

- Urinary retention
- Gastric retention
- Uncontrolled narrow-angle glaucoma
- Hypersensitivity to tolterodine L-tartrate, soya, peanuts, lactose

Relevant warnings and precautions

- increased in heart rate
- interaction with potent CYP3A4 inhibitors
- patient at risk of gastric retention
- patient at risk of urinary retention
- patients with impaired hepatic function

- angioedema
- patients with myasthenia gravis
- patients with controlled narrow-angle glaucoma
- patients with impaired renal function
- Use of contraception in women of childbearing potential

For more information:

Please consult the product monograph at www.toviaz.ca/PM1583 for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece.

The product monograph is also available by calling us at 1-800-XXX-XXXX.

Reference list:

1. Pfizer Canada Inc. TOVIAZ Product Monograph, February 2012.
2. ^{§§}A total of 1964 patients participated in two 12-week, Phase 3 efficacy and safety studies. In these 2 studies combined, 554 patients received TOVIAZ 4 mg/day and 566 patients received TOVIAZ 8 mg/day.
3. Nitti VW et al. Efficacy, safety and tolerability of fesoterodine for overactive bladder syndrome. *J Urol* 2007;178:2488-2494.
4. ^{§§}Randomized, double-blind, placebo-controlled, multicentre study of patients with OAB symptoms including urinary frequency and either urinary urgency or UIUI. Patients were randomized to receive placebo (n=274), TOVIAZ 4 mg (n=283), or TOVIAZ 8 mg (n=279) once-daily for 12 weeks. Number of patients evaluated for urgency episodes/24 hrs was 266, 267, and 267, respectively.
5. Herschorn S et al. Comparison of fesoterodine and tolterodine extended release for the treatment of overactive bladder: A head-to-head placebo-controlled trial. *BJU Int* 2010;105:58-66.
6. ^{††}12-week, double-blind, double-dummy, placebo-controlled, parallel-group, randomized clinical trial of patients with OAB (>8 voids and >1 UIUI episodes/24 hrs in 3-day bladder diaries at baseline) randomized to placebo (n=334); maximum dose of tolterodine ER 4 mg (n=684); or maximum dose of TOVIAZ (4 mg for 1 week then 8 mg for 11 weeks; n=679). Number of patients evaluated for UIUI episodes/24 hrs was 307, 626, and 619, respectively. Baseline means for UIUI episodes/24 hrs were 2.6, 2.5, and 2.4, respectively.
7. Kaplan SA et al. Superior efficacy of fesoterodine over tolterodine extended release with rapid onset: A prospective, head-to-head placebo-controlled trial. *BJU Int* 2011;107:1432-1440.
8. ^{††}12-week, double-blind, double-dummy, placebo-controlled, parallel-group, randomized clinical trial of patients with OAB (>8 voids and >1 UIUI episodes/24 hrs in 3-day bladder diaries at baseline) randomized to placebo (n=478); maximum dose of tolterodine ER 4 mg (n=973); or maximum dose of TOVIAZ (4 mg for 1 week then 8 mg for 11 weeks; n=960). Number of patients evaluated for UIUI episodes/24 hrs was 448, 926, and 908, respectively. Baseline means for UIUI episodes/24 hrs were 2.4, 2.6, and 2.6, respectively.

Figure 9 : Taille de polices de caractères pour du contenu qui n'est **pas** situé sur le recto de l'annonce.

Taille de police de caractères d'au moins 8 points avec un interligne minimum de 10 points pour les titres en caractères gras

Taille de police de caractères d'au moins 8,5 points, avec un interligne minimum de 10 points pour le texte

Taille de police de caractères d'au moins 6 points, avec un interligne de 7 points

Remarque : TOUT LE CONTENU DOIT AVOIR UN CONTRASTE ADÉQUAT ET ÊTRE LISIBLE



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.

Safety and efficacy in pediatric populations have not been established.

Contraindications:

- Urinary retention
- Gastric retention
- Uncontrolled narrow-angle glaucoma
- Hypersensitivity to tolterodine L-tartrate, soya, peanuts, lactose

Relevant warnings and precautions

- increased in heart rate
- interaction with potent CYP3A4 inhibitors
- patient at risk of gastric retention
- patient at risk of urinary retention
- patients with impaired hepatic function

Minimum 8 point font with 10 point leading for bold headings

- angioedema
- patients with myasthenia gravis
- patients with controlled narrow-angle glaucoma
- patients with impaired renal function
- Use of contraception in women of childbearing potential

Minimum of 8.5 point font with 10 point leading for text

For more information:

Please consult the product monograph at www.toviaz.ca/PM1583 for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece.

The product monograph is also available by calling us at 1-800-XXX-XXXX.

Reference list:

1. Pfizer Canada Inc. TOVIAZ Product Monograph, February 2012.
2. Nitti VW et al. Efficacy, safety and tolerability of fesoterodine for overactive bladder syndrome. *J Urol* 2007;178:2488-2494.
3. Herschorn S et al. Comparison of fesoterodine and tolterodine extended release for the treatment of overactive bladder: A head-to-head double-blind, double-dummy, placebo-controlled, parallel-group, randomized clinical trial of patients with OAB (>8 voids and >1 UII episodes/24 hrs in 3-day bladder diaries at baseline) randomized to placebo (n=334), maximum dose of tolterodine ER 4 mg (n=94), or maximum dose of TOVIAZ (4 mg for 1 week then 8 mg for 11 weeks; n=979). Number of patients evaluated for UII episodes/24 hrs was 307, 626, and 619, respectively. Baseline means for UII episodes/24 hrs were 2.6, 2.5, and 2.4, respectively.
4. Kaplan SA et al. Superior efficacy of fesoterodine over tolterodine extended release with rapid onset. A prospective, head-to-head placebo-controlled trial. *BJU Int* 2011;107:1432-1440.
5. 12-week, double-blind, double-dummy, placebo-controlled, parallel-group, randomized clinical trial of patients with OAB (>8 voids and >1 UII episodes/24 hrs in 3-day bladder diaries at baseline) randomized to placebo (n=478), maximum dose of tolterodine ER 4 mg (n=973), or maximum dose of TOVIAZ (4 mg for 1 week then 8 mg for 11 weeks; n=960). Number of patients evaluated for UII episodes/24 hrs was 448, 926, and 908, respectively. Baseline means for UII episodes/24 hrs were 2.4, 2.6, and 2.6, respectively.

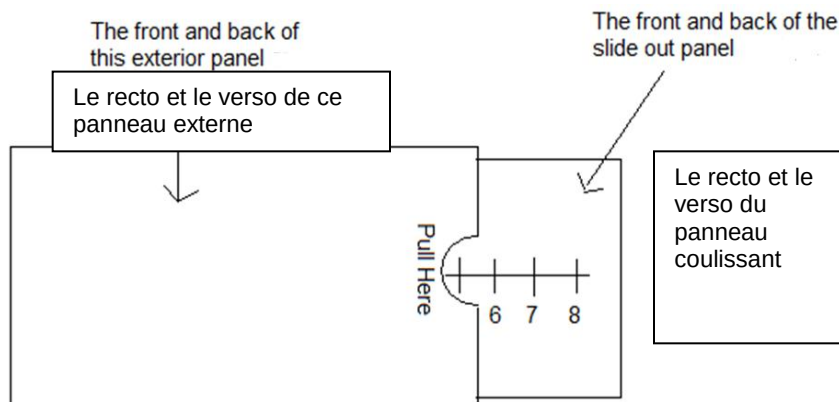
Minimum 6 point font with 7 point leading

Note: ALL CONTENT MUST BE IN GOOD CONTRAST AND MUST BE LEGIBLE

Autres utilisations clés du niveau moyen pour mener au niveau ultime d'énoncé de juste équilibre

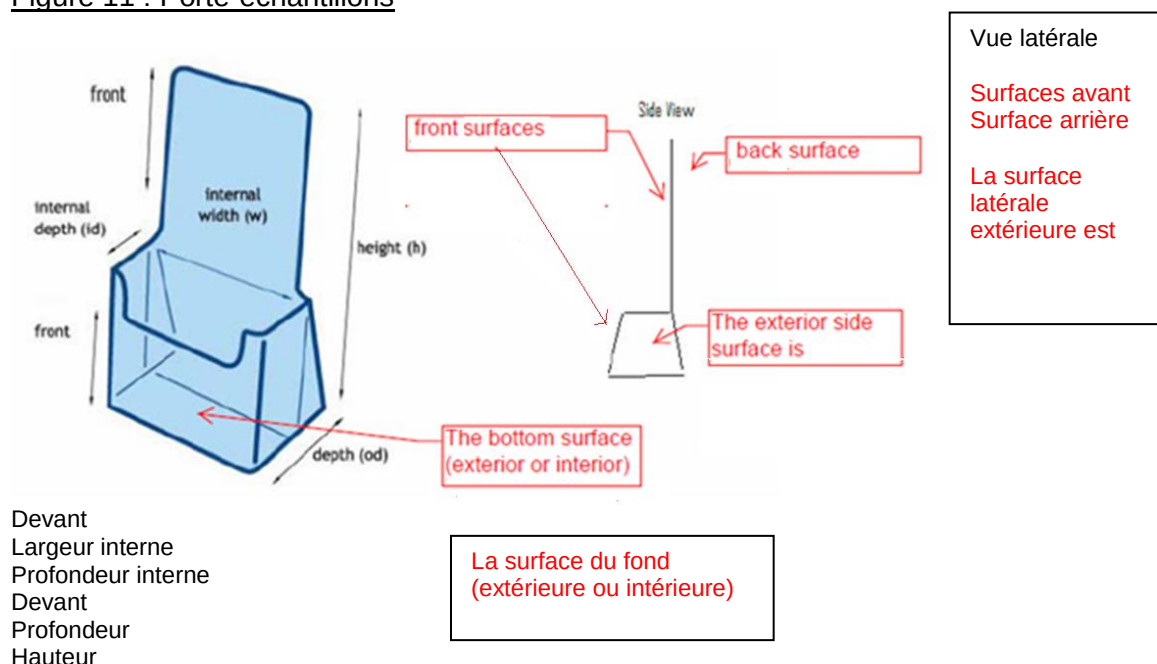
Pour une règle coulissante (voir à la Figure 10), la surface publicitaire principale est confinée en règle générale aux faces extérieures (recto et verso). La règle elle-même, qui coulisse, ne fait pas partie de la surface publicitaire principale. Le fabricant a le choix de placer un niveau moyen d'énoncé de juste équilibre sur la face externe, pour indiquer au lecteur qu'il doit enlever la règle pour accéder au niveau ultime d'énoncé de juste équilibre. Il est même possible que la règle se déplie, ce qui offre une plus grande surface. Le lecteur replie ensuite la règle et la glisse facilement en place dans l'étui pour continuer à utiliser l'outil publicitaire. D'autres outils publicitaires offrent des possibilités similaires, par exemple les bandes publicitaires, les affichettes de gondoles et les affichettes chevalet.

Figure 10 : Règle coulissante



Sur un porte-échantillons (voir la figure 11), la surface publicitaire principale est confinée en règle générale aux panneaux avant et de côté. Le panneau arrière est généralement appuyé contre la paroi de l'armoire. Un niveau moyen d'énoncé de juste équilibre peut être inscrit sur les panneaux avant et de côté pour indiquer au professionnel de la santé de sortir le porte-échantillons de sous l'armoire et de regarder le panneau arrière où se trouve le niveau ultime d'énoncé de juste équilibre. Vous remarquerez que le niveau ultime d'énoncé de juste équilibre ne peut pas apparaître sur les panneaux intérieurs ni sur le panneau du fond car il faudrait se contorsionner ou vider le porte-échantillons pour lire un énoncé sur ces surfaces. C'est pour des raisons similaires que le niveau ultime d'énoncé de juste équilibre ne pourrait pas apparaître sur le dessus ni sur le fond des affichettes de gondoles posées sur les étagères (c.-à-d. il faudrait retirer le produit pour que le texte de l'énoncé soit visible).

Figure 11 : Porte-échantillons



Dans les sites Web protégés réservés aux professionnels de la santé, les annonces dans des bannières électroniques qui contiennent des allégations sur des produits doivent impérativement comporter un énoncé de juste équilibre. Cette exigence n'est pas respectée si l'énoncé de juste équilibre est relégué à un clic publicitaire car cela entraîne une séparation des allégations et de l'énoncé de juste équilibre. Cependant, le niveau moyen d'énoncé de juste équilibre peut apparaître sur le devant de la bannière avec un clic publicitaire qui envoie directement au niveau ultime d'énoncé de juste équilibre. Dans un tel cas, le niveau ultime d'énoncé de juste équilibre devrait être présenté sur le devant de la destination du lien Internet (c.-à-d. il ne devrait pas être relégué à un clic publicitaire apparaissant dans le lien Internet et qui nécessiterait alors un clic supplémentaire). Bien que cela disqualifie la destination du lien Internet d'être exemptée de l'agrément préalable, cette option simplifie la communication des allégations thérapeutiques sur les bannières électroniques. Lorsque plusieurs cadres sont utilisés, l'indication devrait apparaître sur (ou avant) le premier cadre contenant des allégations d'avantage marketing explicites (veuillez vous reporter au « Document d'orientation sur le placement des indications dans les publicités »).

Pour connaître l'utilisation des niveaux moyens d'énoncés de juste équilibre sur la page d'accueil des sites Web de produits, veuillez vous reporter au document du CCPP « Document d'orientation sur la sélection et le placement du niveau de base de l'énoncé de juste équilibre ».

La destination du lien Internet

L'adresse URL ou le lien électronique peuvent mener à toutes les pages de destination énumérées à l'article 7.3 du code du CCPP.

Les destinations des liens Internet sur un produit contrôlé par une entreprise/un agent ou des sites d'entreprises qui ont un contenu supplémentaire aux éléments énumérés à l'article 7.3.2b doivent être soumises au CCPP pour révision sous la forme d'un SPP distinct. Tout le contenu visible de ces pages (y compris, sans pour autant s'y limiter, des liens et/ou des commandes de menus) doit être révisé dans le contexte du produit de marque.