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**PRISTIQ Email #1– Efficacy**

COPY REVISIONS

Original v.1: August 28, 2015

Original v.2: September 9, 2015

Original v.3: September 16, 2015

Original v.4 (Rev SetC): September 24, 2015

PAAB v.5: October 22, 2015

PAAB v. 6: October 30, 2015

Update v.7: November 9, 2015

Proofreading v.8: November 13, 2015

SUBJECT: PRISTIQ’s demonstrated efficacy

VISUAL: PATIENT VISUAL

LOGO: PrPRISTIQ®

COPY: PRISTIQ is indicated for the symptomatic relief of major depressive disorder.1

HEAD: **In major depressive disorder, her doctor calls it**

**“demonstrated improved functional outcomes”**

**She calls it “helping her at work”\***

HEAD: **Choose PRISTIQ**

HEAD: **Demonstrated improvements in functional outcomes: social life, family life, and work**

(secondary endpoints).

COPY:

* At Week 8, PRISTIQ 50 mg and 100 mg demonstrated significant improvements in functional outcomes from baseline vs. placebo, as measured by the Sheehan Disability Scale (SDS).2**†**

CHART TITLE: **Reductions from baseline in individual SDS scores2‡**

CHART:

Family life Social life Work life

**Improvement**

**FPO**

Y-AXIS: Adjusted mean change from baseline in SDS scores

0, -0.5, -1.0, -1.5, -2.0, -2.5, -3.0, -3.5. -4.0

X-AXIS: Placebo (n=160)

PRISTIQ 50 mg (n=163)

PRISTIQ 100 mg (n=157)

Placebo (n=160)

PRISTIQ 50 mg (n=163)

PRISTIQ 100 mg (n=157)

Placebo (n=148)

PRISTIQ 50 mg (n=156)

PRISTIQ 100 mg (n=149)

COPY: Improvement

DISCLAIMER: Adapted from Boyer P, *et al.* 2008.

CHART DATA:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Family life** | | | **Social life** | | | **Work life** | | |
| Placebo | 50 mg | 100 mg | Placebo | 50 mg | 100 mg | Placebo | 50 mg | 100 mg |
| -2.2 | -3.0 | -3.2 | -2.3 | -3.2 | -3.4 | -2.2 | -2.9 | -3.2 |
|  | *p*=0.002 vs. placebo | *p*<0.001 vs. placebo |  | *p*=0.003 vs. placebo | *p*<0.001 vs. placebo |  | *p*=0.010 vs. placebo | *p*<0.001 vs. placebo |

BALANCE:

**Safety Information**

**Clinical Use:**

* PRISTIQ is not indicated for use in children under the age of 18
* The short-term efficacy of PRISTIQ has been demonstrated in placebo-controlled trials of up to 8 weeks
* The efficacy of PRISTIQ in maintaining an antidepressant response for up to 26 weeks, following response during 20 weeks of acute, open-label treatment, was demonstrated in a placebo-controlled trial

**Contraindications:**

* Concomitant use with monoamine oxidase inhibitors (MAOIs) or within the preceding 14 days
* Hypersensitivity to venlafaxine hydrochloride

**Most Serious Warnings and Precautions:**

* **Behavioural and emotional changes, including self-harm:** SSRIs and other newer antidepressants may be associated with:
* Behavioural and emotional changes including and increased risk of suicidal ideation and behaviour
* Severe agitation-type adverse events coupled with self-harm or harm to others
* Suicidal ideation and behavior; rigorous monitoring
* **Discontinuation symptoms:** should not be discontinued abruptly. Gradual dose reduction is recommended

**Other Relevant Warnings and Precautions:**

* Concomitant use with venlafaxine not recommended
* Allergic reactions such as rash, hives or a related allergic phenomenon
* Bone fracture risk with SSRI/SNRI
* Increases in blood pressure and heart rate (measurement prior to and regularly during treatment)
* Increases cholesterol and triglycerides (consider measurement during treatment)
* Hyponatremia or Syndrome of Inappropriate Antidiuretic Hormone (SIADH) with SSRI/SNRI
* Potential for GI obstruction
* Abnormal bleeding SSRI/SNRI
* Interstitial lung disease and eosinophilic pneumonia with venlafaxine
* Seizures
* Narrow angle glaucoma
* Mania/hypomania
* Serotonin syndrome or neuroleptic malignant syndrome-like reactions

**For More Information:**

Please consult the product monograph at <http://pfizer.ca/en/our_products/products/monograph/226> 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 1-800-463-6001.

FOOTNOTES:

\*The SDS measures the functional impairment that depressive symptoms have on a patient’s family life, social life, and work.3 A decrease in SDS score represents improved functional outcomes.2

†A randomized, double-blind, parallel-group, placebo-controlled, multicentre trial involving 485 patients with MDD and a 17-item Hamilton Rating Scale for Depression (HAM-D17) total score ≥20, a HAM-D17 item 1 score ≥2, and a Clinical Global Impression-Severity (CGI-S) scale score ≥4. Patients were randomized to receive fixed-dose PRISTIQ 50 mg/day, PRISTIQ 100 mg/day, or placebo for 8 weeks. Primary endpoint was change from baseline to last observation carried forward (LOCF) in HAM-D17 total score. Secondary endpoints included change from baseline to LOCF in SDS individual domain scores.

‡LOCF final evaluation, intent-to-treat (ITT) population.

REFERENCE:

**References:**

1. PRISTIQ Product Monograph, Pfizer Canada Inc., December 3, 2014. 2. Boyer P, Montgomery S, Lepola U*, et al.* Efficacy, safety, and tolerability of fixed-dose desvenlafaxine 50 and 100 mg/day for major depressive disorder in a placebo-controlled trial. *Int Clin Psychopharmacol*. 2008; 23(5):243–253. 3. Sheehan DV. Rush AJ, *et al.,* editors. *Handbook of psychiatric measures*. 2000.

COPY: For more information, visit PristiqPro.ca

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FOOTER:  
LOGOS: PAAB, Rx&D

CODE: CA0115PRI013E

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|  |

LOGO: Pfizer

LOGO: Pfizer, Count on PRISTIQ for powerful symptom relief

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