Pfizer Saudi Limited
Commercial reg. no. 4602004906
Business Gate, Airport Road
P.O.Box 6722, Riyadh 11452
Tel: 2021800 – Fax: 2021810.
SAUDI ARABIA

Direct Healthcare Professional Communication (DHPC)

May 18, 2021

Warning about the Increased Risk of Postpartum Haemorrhage Associated with the Use of Lustral (Sertraline), Efexor (Venlafaxine) and Pristiq (Desvenlafaxine) in Pregnant Women.

Dear Health Care Provider,

Pfizer in Agreement with the Saudi Food and Drug Authority (SFDA) would like to inform you of the potential risk of postpartum haemorrhage associated with the use of Lustral (Sertraline), Efexor (Venlafaxine) and Pristiq (Desvenlafaxine) in pregnant women close to delivery. The Professional Information (PI) and Patient Information Leaflet (PIL) of these products will be amended to reflect this safety issue.

Summary

Data from several observational studies have shown an increased risk (less than 2-fold) of postpartum haemorrhage with the use of Lustral (Sertraline), Efexor (Venlafaxine) and Pristiq (Desvenlafaxine), in pregnant women near the time of delivery. The use of Lustral (Sertraline), Efexor (Venlafaxine) and Pristiq (Desvenlafaxine) near the end of pregnancy may be associated with an increased risk of heavy vaginal bleeding shortly after birth, more specifically in patients who have history of bleeding disorders.

Advice to Healthcare Professionals

- Postpartum haemorrhage may occur in patients exposed to Lustral (Sertraline), Efexor (Venlafaxine) and Pristiq (Desvenlafaxine) in the late stage of pregnancy.
- Caution is advised in patients taking Lustral (Sertraline), Efexor (Venlafaxine) and Pristiq (Desvenlafaxine) with a history of bleeding disorders or patients predisposed to bleeding.
- Discontinuation of treatment: If Pristiq (Desvenlafaxine)/Lustral (Sertraline)/Efexor (Venlafaxine) therapy has to be discontinued, it should be tapered. Abrupt discontinuation may lead to withdrawal symptoms (please refer to the PI for additional information).

Patient safety and the appropriate use of our medicines is of the utmost importance to Pfizer and we continuously evaluate safety for all our medicines through ongoing clinical research, analysis and routine pharmacovigilance surveillance.

Reporting Adverse Events

Healthcare professionals are reminded to report all suspected adverse events including those associated with Lustral (Sertraline), Efexor (Venlafaxine) and Pristiq (Desvenlafaxine) to:

- The National Pharmacovigilance & Drug safety Centre (NPC) at Saudi Food and Drug Authority (SFDA)
  SFDA Call Center: 19999
  Toll Free Phone: 8002490000
  Fax: +966-11-2057662
  E-mail: npc.drug@sfda.gov.sa
  Website: http://ade.sfda.gov.sa/
- Pharmacovigilance Department in the company
  E-mail: SAU.AEReporting@pfizer.com
  Phone: +966 12 2293500

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Table 1: Products

Company	Product	Active Ingredient
Pfizer Saudi Limited	Pristiq 50 mg Extended-release tablets	Desvenlafaxine
Pfizer Saudi Limited	Efexor® XR 75 mg and 150 mg capsules	Venlafaxine
SPIMACO Under license from Pfizer INC., New York, USA	Lustral® Tablets 50 mg	Sertraline

Efexor® (Venlafaxine) Indications:

1. Treatment of major depressive episodes.
2. For prevention of recurrence of major depressive episodes.
3. Treatment of generalized anxiety disorder.
4. Treatment of social anxiety disorder.
5. Treatment of panic disorder, with or without agoraphobia.

Pristiq® (Desvenlafaxine) Indication:

Treatment of adults with major depressive disorder (MDD)

Lustral® (Sertaline) Indications:

1. Treatment of Major depressive episodes. Prevention of the recurrence of major depressive episodes.
2. Treatment of Panic disorder, with or without agoraphobia.
3. Treatment of Obsessive-compulsive disorder (OCD) in adults and pediatric patients aged 6-17 years.
4. Treatment of Social anxiety disorder.
5. Treatment of Post-Traumatic Stress Disorder (PTSD).

Sincerely,

Ahmed Osman

Medical Manager
Pfizer Saudi Arabia