

Date: 29 April, 2015

Direct Healthcare Professional Communication on restriction of combined use of medicines affecting the renin-angiotensin aldosterone system (RAAS) for medicinal products containing lisinopril:

LISORILL®

Dear Healthcare Provider,

Riyadh Pharma would like to inform you about restrictions on combining different classes of medicines that act on the renin-angiotensin aldosterone system (RAAS), a hormone system that controls blood pressure and the volume of fluids in the body. This group of medicines (called RAAS-acting agents) has three main classes: angiotensin-receptor blockers (ARBs), angiotensin-converting enzyme inhibitors (ACE-inhibitors) and direct renin inhibitors such as aliskiren. Combination of medicines from any two of these classes should not be used and, in particular, in patients with diabetes mellitus or renal impairment.

information on the safety Concern

- Combination therapy of direct renin inhibitors such as aliskiren with ACEI or ARB may cause an increased risk of hyperkalemia, worsening of the kidney function and hypotension. Therefore, this combination should not be used, especially in patients with diabetes mellitus or renal impairment.
- Combination therapy of ACEI and ARB drugs may cause an increased risk of hyperkalemia, worsening of the kidney function and hypotension. Therefore, this combination should not be used, especially in patients with diabetes mellitus or renal impairment.
- If dual blockade therapy is considered absolutely necessary, this should only occur under specialist supervision and subject to frequent close monitoring of renal function, electrolytes and blood pressure.

The information in this letter has been approved by the Saudi Food and Drug Authority

For Reporting Adverse Events.

Riyadh Pharma will continue to monitor the safety of LISORIL through established reporting mechanisms and notify regulatory authorities of any serious adverse events for evaluation. You can assist us in monitoring the safety of LISORIL by reporting suspected adverse events associated with the use of LISORIL to:

MEDICAL & COSMETIC PRODUCTS Company

Abdel Malick Bin Marwan St. - P.O. Box 442, Riyadh 11411



The National Pharmacovigilance and Drug Safety Center
Fax: +966-11-2057662
Email: Npc.drug@sfda.gov.sa
Online: <http://ade.sfda.gov.sa>
Toll free phone: 8002490000

Or

Pharmacovigilance Department in Riyadh Pharma
Fax: +966-11-4065260
Tel: +966-11-4026150 ext. 213
Email: abedf@riyadhpharma.com

Sincerely Yours,



Abed A. El-Fawal
Medical Affairs Managers

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