16th January 2020

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

Olmepress (Olmesartan medoxomil)

Dear Healthcare Professional,

Laboratorios CINFA S.A. 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.

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- 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.

The Summary of Products Characteristics (SPC) and patient leaflet of Olmepress 10 mg film-coated tablets, Olmepress 20 mg film-coated tablets and Olmepress 40 mg film-coated tablets in Saudi Arabia is updated to reinforce the safety of treated patients.

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance and Drug Safety Center (NPC) or CINFA´s Local representative.
The National Pharmacovigilance and Drug Safety Center

By email: npc.drug@sfda.gov.sa
Or by fax: +966 11 2057662
Or by online: https://ade.sfda.gov.sa/

CINFA´s local representative in Saudi Arabia:

By Email: eelaji@cigalah.com.sa / drug-safety@cigalah.com.sa
By mobile: +966542484174

Yours sincerely,

Laboratorios Cinfa, S.A.

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