

Our ref : 122
Date : Tuesday 30/12/2014

إشارتنا :
التاريخ :

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

Diovan®
Exforge®
Exforge HCT®
Co-Diovan®
Rasilez HCT®

Dear Healthcare Professional,

Novartis 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.

Novartis Consulting AG - Scientific Office

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ترخيص وزارة التجارة رقم ٣

الرياض	جدة	الدمام
ص، ب : ١٦٠٣٢	ص . ب : ٨٦٤٠	ص . ب : ٦٥٠٣
الرياض : ١١٤٦٤	جدة : ٢١٤٩٢	الدمام : ٣١٤٥٢
تلفون : ٤٦٥ ٨٨٨٢	تلفون : ٦٦٩ ٥٦٦٦	تلفون : ٨٣٤ ٣١٧٤
تليفاكس : ٤٦٤ ٨١٢٧	تليفاكس : ٦٦٣ ٣٥٣٤	تليفاكس : ٨٣٤ ٤٢٠٠

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إشارتنا :

Date :

التاريخ :

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

The Summary of Products Characteristics (SPC) and Patient Information Leaflet (PIL) of Diovan, Exforge, Exforge HCT, Co-Diovan, and Rasilez HCT in Saudi Arabia will be updated shortly 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):

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

Or

Pharmacovigilance department in Novartis:

Phone: +966112658100
Fax: +966112658107
Email: adverse.events@novartis.com

Yours sincerely,**Riyadh Al Malahi**
DS&E Responsible**Novartis Consulting AG - Scientific Office**

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مكتب شركة نوفارتس كونسلتنغ إي جي المكتب العلمي
ترخيص وزارة التجارة رقم ٣

الرياض	جدة	الدمام
ص، ب : ١٦٠٣٢	ص . ب : ٨٦٤٠	ص . ب : ٦٥٠٣
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تليفاكس : ٤٦٤ ٨١٢٧	تليفاكس : ٦٦٣ ٣٥٣٤	تليفاكس : ٨٣٤ ٤٢٠٠