

**הנדון: Co-Diovan 80/12.5mg, 160/12.5mg, 160/25mg film coated tablets**  
**קו-דיובאן 80/12.5 מ"ג, 160/12.5 מ"ג, 160/25 מ"ג טבליות מצופות**

התכשירים שבנדון רשומים בישראל להתוויות הבאות:

Co-Diovan 80/12.5mg:

Co-Diovan is indicated for the treatment of hypertension in patients in whom combination therapy is appropriate.

Co-Diovan 160/12.5mg, 160/25mg:

Co-Diovan is indicated for the treatment of hypertension in patients whose blood pressure is not adequately controlled by monotherapy.

This fixed combination should be used as second-line therapy.

המרכיבים הפעילים:

Co-Diovan 80/12.5mg: Valsartan 80mg, Hydrochlorothiazide 12.5mg

Co-Diovan 160/12.5mg: Valsartan 160mg, Hydrochlorothiazide 12.5mg

Co-Diovan 160/25mg: Valsartan 160mg, Hydrochlorothiazide 25mg

בינואר 2014 עודכנו העלון לרופא והעלון לצרכן של התכשירים כדלקמן (קו תחתי – תוספת טקסט, קו חוצה – מחיקת טקסט):

**עלון לרופא:**

#### **4 Dosage and administration**

##### **Dosage**

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Co-Diovan must not be used in combination with aliskiren in patients with diabetes mellitus.

##### **Renal impairment**

..... Concomitant use of Co-Diovan with aliskiren is contraindicated in patients with renal impairment (GFR < 60 ml/min/1.73 m<sup>2</sup>) (see section 5).

##### **5 Contraindications**

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The Concomitant use of angiotensin receptor antagonists (ARBs) - including valsartan- or of angiotensin-converting enzyme inhibitors (ACEIs) with aliskiren is contraindicated in patients with type-2 diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m<sup>2</sup>) (see sections 6 Warnings and precautions, 8 Interactions, subsection dual RAS blockade & 11 Pharmacodynamics).

**Novartis Pharma Services AG**

**Israeli Branch**

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**נוברטיס פארמה סרוויסס איי ג'י**

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## 6 Warnings and precautions

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### Patients with renal impairment

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The use of ARBs - including valsartan- or of ACEIs with aliskiren ~~should be avoided~~ is contraindicated in patients with ~~severe~~ renal impairment (GFR < ~~30~~60 mL/min) (see section ~~5~~ Contraindications & 8 Contraindications-Interactions, subsection dual blockade of the RAS).

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### Dual Blockade of the Renin-Angiotensin System (RAS)

Hypotension, syncope, stroke, hyperkalaemia, and changes in renal function (including acute renal failure) have been reported in susceptible individuals, especially if combining medicinal products that affect this system (see section 11). Dual blockade of the renin-angiotensin-aldosterone system by combining valsartan with aliskiren is therefore not recommended.

Caution is required while co-administering ARBs, including valsartan, with other agents blocking the RAS such as ACEIs ~~or aliskiren~~ (see section 8 Interactions, subsection dual blockade of the RAS).

## 7 Adverse drug reactions

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The combination of valsartan with aliskiren is contraindicated in patients with diabetes mellitus or renal impairment (GFR<60 ml/min/1.73m<sup>2</sup>) and is not recommended in other patients (see sections 5, 6, 11).

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**Table 7-2 Frequency of adverse drug reactions with valsartan**

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Skin and subcutaneous tissue disorders	
Not known	Angioedema, rash, <u>dermatitis bullous</u> , pruritus

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## 8 Interactions

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### Valsartan

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#### Dual blockade of the Renin-Angiotensin-System (RAS) with ARBs, ACEIs, or aliskiren:

The combination of ARBs - including valsartan - or of ACEIs with aliskiren, is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 mL/min/1.73m<sup>2</sup>) (see section 5 contraindications) and is not recommended in other patients.

~~The concomitant use of ARBs, including valsartan, with other agents acting on the RAS is associated with an increased incidence of hypotension, hyperkalemia, and changes in renal~~

~~function compared to monotherapy. It is recommended to monitor blood pressure, renal function and electrolytes in patients on Co-Diovan and other agents that affect the RAS (see section 6 Warnings and precautions).~~

~~The concomitant use of ARBs – including valsartan – or of ACEIs with aliskiren, should be avoided in patients with severe renal impairment (GFR < 30 mL/min) (see section 6 Warnings and precautions).~~

~~The concomitant use of ARBs – including valsartan – or of ACEIs with aliskiren is contraindicated in patients with Type 2 diabetes (see section 5 Contraindications).~~

**Potassium:** Concomitant use with potassium supplements, potassium-sparing diuretics, salt substitutes containing potassium, or other drugs that may alter potassium levels (heparin, etc.) should be used with caution and with frequent monitoring of potassium.

The combination of Co-Diovan with Aliskiren is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m<sup>2</sup>) and is not recommended in other patients (see sections 5&6).

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#### עלון לצרכן:

#### אין להשתמש בתכשיר אם:

.....

יש לך רמה גבוהה של סוכר בדם ואתה סובל מסוכרת מסוג 2 (נקראת גם סוכרת שאינה תלויה באינסולין) ואתה לוקח תרופה להורדת לחץ דם המכילה אליסקירן (כגון ראסילז) באותו הזמן.  
אתה סובל מליקוי בתפקוד הכליה ואתה לוקח תרופה להורדת לחץ דם המכילה אליסקירן (כגון ראסילז) באותו הזמן.

#### 4. תופעות לוואי:

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תופעות הלוואי הבאות נצפו במחקרים קליניים עם קו-דיובאן: .....  
ולסרטן: ..... שלפוחיות בעור (סימן לדלקת עור) [דרמטיטיס] שלפוחיתית); .....

העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על-ידי פניה לבעל הרישום.

בברכה,

אסנת מירון - עוזרי  
רוקחת ממונה

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