# הודעה על החמרה ( מידע בטיחות) בעלון לרופא

# (מעודכן 05.2013)

**תאריך** 12 לאוגוסט 2013**\_**

**שם תכשיר באנגלית ומספר הרישום**: Atacand 4 mg, 8 mg and 16 mg tablets

**מס' רישום: מספר רישום:**

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109 09 29184, p

109 1029185

**שם בעל הרישום** \_\_\_ אסטרהזניקה (ישראל) בע"מ **\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

טופס זה מיועד לפרוט ההחמרות בלבד !

עלון לרופא:

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| **ההחמרות המבוקשות** | | |
| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **POSOLOGY** | initial dose of 2 mg once daily is recommended in patients with mild to moderate hepatic impairment. The dose may be adjusted according to response. There is no experience in patients with severe hepatic impairment. | Patients with hepatic impairment: Dose titration is recommended in patients with mild to moderate chronic liver disease, and initial dose of 2 mg once daily is recommended ~~a lower initial dose of 4 mg should be considered~~ The dose may be adjusted according to response.  Atacand ~~should not be used~~ is contraindicated in patients with severe hepatic impairment  and/or cholestasis (see section 4.3). |
| **contraindications** | Hypersensitivity to any component of Atacand®.  Pregnancy and lactation (see section 4.6 Pregnancy and lactation). | Severe hepatic impairment and/or cholestasis.  The use of candesartan cilexetil in combination with aliskiren-containing medicines in  patients with diabetes mellitus (type I or II) or with moderate to severe renal impairment  (GFR<60ml/min/1.73m2). |
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| **Special Warnings and Special Precautions for Use** | Hypotension may occur during treatment with Atacand® in heart failure patients As described for other agents acting on the renin-angiotensin-aldosterone system, it may also occur in hypertensive patients with intravascular volume depletion | changes in renal function including acute renal failure may be anticipated in susceptible patients treated with Atacand®.  Patients whose renal function may depend, in part, on the activity of the renin-angiotensin system (e.g., patient with renal artery stenosis, chronic kidney disease, severe heart failure, or volume depletion) may be at particular risk of developing oliguria, progressive azotemia or acute renal failure when treated with ATACAND. Consider withholding or discontinuing therapy in patients who develop a clinically significant decrease in renal function on ATACAND.  In the CHARM program (heart failure patients), the incidence of abnormal renal function (e.g., creatinine increase) was 12.5% in patients treated with ATACAND versus 6.3% in patients treated with placebo. The incidence of abnormal renal function (e.g., creatinine increase) leading to drug discontinuation in ATACAND-treated patients was 6.3% compared with 2.9% in placebo-treated patients. In the CHARM-Added program, where candesartan or placebo was given in addition to ACE inhibitors, the incidence of abnormal renal function (e.g., creatinine increase) was 15% in patients treated with ATACAND versus 9% in patients treated with placebo.    ~~Hepatic impairment~~  ~~There is only limited experience in patients with severe hepatic impairment and/or cholestasis~~.  ATACAND can cause symptomatic hypotension.  Symptomatic hypotension is most likely to occur in patients who have been volume and/or salt depleted as a result of prolonged diuretic therapy, dietary salt restriction, dialysis, diarrhea, or vomiting. Patients with symptomatic hypotension may require temporarily reducing the dose of ATACAND, diuretic or both, and volume repletion. Volume and/or salt depletion should be corrected before initiating therapy with ATACAND.  In the CHARM program (heart failure patients), hypotension was reported in 18.8% of patients on ATACAND versus 9.8% of patients on placebo. The incidence of hypotension leading to drug discontinuation in ATACAND-treated patients was 4.1% compared with 2.0% in placebo-treated patients. In the CHARM-Added program, where candesartan or placebo was given in addition to ACE inhibitors, hypotension was reported in 22.6% of patients treated with ATACAND versus 13.8% treated with placebo *.*  Monitoring of blood pressure is recommended during dose escalation and periodically thereafter.  Dual blockade of the renin-angiotensin-aldosterone system by combining candesartan  cilexetil and angiotensin receptor blockers, ACE inhibitors or aliskiren is not recommended since there is an increased risk of hypotension,hyperkalaemia and changes in renal function (including acute renal failure) compared to monotherapy..  Closely monitor blood pressure, renal function and electrolytes in patients on ATACAND and other agents that affect the RAAS.  *The use of candesartan cilexetil with aliskiren is contraindicated in patients with diabetes mellitus (type I or II) or moderate to severe renal impairment (GFR<60ml/min/1.73m2) (see section 4.3).*  ATACAND can cause symptomatic hypotension. Hypotension may occur during treatment with Atacand® in heart failure patients As described for other agents acting on the renin-angiotensin-aldosterone system, it may also occur in hypertensive patients with intravascular volume depletion or salt depletion.  . |
| **Interaction with Other Medicaments and Other Forms of Interaction** |  | The combination of candesartan cilexetil with aliskiren-containing medicine is contraindicated in patients with diabetes mellitus (type I or II) or moderate to severe renal impairment (GFR<60ml/min/1.73m2) and is not recommended in other patients (see section 4.3 and section 4.4). |
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| **Adverse events** |  | Pharyngitis  Rhinits  Rare reports of rhabdomyolysis have been reported in patients receiving angiotensin II receptor blockers. |

**עלון לצרכן**

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| **ההחמרות המבוקשות** | | |
| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **אין להשתמש בתרופה** |  | * אין להשתמש באטקנד אם הינך נוטל תרופה להורדת לחץ דם המכילה אליסקירן aliskiren ויש לך סוכרת * אין להשתמש באטקנד אם הינך נוטל תרופה להורדת לחץ דם המכיל אליסקירן aliskiren ויש לך בעיות בתפקוד הכליות |
| **אם אתה לוקח תרופות אחרות** |  | אין להשתמש באטקנד אם הינך נוטל תרופה להורדת לחץ דם המכילה אליסקירן aliskiren ויש לך סוכרת  אין להשתמש באטקנד אם הינך נוטל תרופה להורדת לחץ דם המכילה אליסקירן aliskiren ויש לך בעיות בכליות |
| **תופעות לוואי** |  | כאב גרון (דלקת בגרון)  גודש באף (דלקת בריריות האף) |
| **לפני הטיפול בתרופה ספר לרופא אם:** |  | אם אתה סובל ממחלת בלוטת יתרת הכליה (אדרנל) הנקראת תסמונת קונס ((Conn's |
| **כיצד תשתמש בתרופה** |  | * תרופה זו אינה מיועדת בדרך כלל לילדים (מתחת לגיל 18). |
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